VOLUME 12 NUMBER 6

Food-Drug-Cosmetic Law Journal

JUNE • 1957

AOAC Methods of Analysis . . . W. B. WHITE

The Consumer Looks at Chemicals in Our Food . . . . . GEORGE P. LARRICK

Effect of a Substance Natural to a Product on the Implied Warranty of Fitness . . . . . QUENTIN H. WOOD

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A COMMERCE CLEARING HOUSE PUBLICATION

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law; (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

The late **W. B. White** — whose "AOAC Methods of Analysis" is reprinted from our magazine for December, 1946—as Chief of the Food and Drug Administration's Division of Food, once described the ideal federal food-and-drug chemist as being zealous for public service, self-effacing, cooperative, sound in judgment, possessed of initiative, tactful and agreeable. All these qualifications were described as being in addition to the fundamental "sterner virtues" of honesty, "intestinal fortitude," thoroughness, fixity of purpose, neatness, alertness, resourcefulness, speed, calmness and love of contest. (See FOOD DRUG COSMETIC LAW JOURNAL, June, 1952.) Dr. White went on to say of these suggestions: "After you read them you may conclude that I am describing an ideal chemist who never existed on sea or land. Probably this is so, and yet this, in a sense, is what you are asking for. . . ."

Dr. White's contributions to the development of food and drug law would indicate that he closely approached, in his personal qualifications, the scientist he described. He headed the Division of Food for nearly 21 years before his death in February, 1951, and had served as chairman-editor on the editorial committee of the *Journal of the A. O. A. C.* Dr. White had also contributed several other articles to our own JOURNAL between 1946 and 1949.

George P. Larrick succeeded Charles W. Crawford as Commissioner of Food and Drugs in 1954. He had served as Deputy Commissioner since 1951, and has been a career employee of FDA for almost 35 years. His first post was as an inspector at Cincinnati, soon after his college days at Wittenberg College and Ohio State University. In 1928, he took up administrative duties at Washington, and two years later was assigned to general administrative direction of FDA's inspection force. He was Assistant Commissioner from 1945 to 1948 and Associate Commissioner from 1948 to 1951.

Quentin H. Wood received his LL. B. degree from Boston University in 1949 and an LL. M. degree from Northwestern University the following year. He joined the United States Navy, where he served as a legal specialist in the Judge Advocate General's Office until 1954. Since that time, Mr. Wood has been associated with the law department of Swift & Company, at Chicago. He is a member of the Massachusetts and the Illinois bars.

The writer of "Medicated Feeds and the Federal Law," **Ralph F. Kneeland, Jr.,** is assistant to the Director of the Bureau of Enforcement, FDA. His article is derived from a speech delivered at a meeting of the Colorado Grain, Milling and Feed Dealers Association, at Denver, in February of this year.

Mr. Kneeland joined FDA in 1935 as an inspector; he was transferred to Washington, D. C., in 1939. He also served as chemist and biochemist with FDA.

John A. Gosnell's "Food-Additive Legislation—A Review of Fundamentals" is a speech from the January 23 meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, at New York City. He is an attorney, Washington, D. C.

The writer of the continuing feature, "Christopher Comments," is Thomas W. Christopher, associate dean and professor of law at Emory University, in Georgia.

"The Scientists' Forum" is written by **Bernard L. Oser,** who is vice president and director of Food Research Laboratories, Inc., Long Island City, New York.

Meeting of Drug Men

The annual meeting of the American Pharmaceutical Manufacturers' Association was held at the Greenbrier Hotel, White Sulphur Springs, West Virginia, May 27-29.

Among the speakers was Aims C. McGuinness, M. D., Special Assistant to the Secretary for Health and Medical Affairs, United States Department of Health, Education, and Welfare. He said, in part:

". . . I not only am willing but glad to speak here about certain things I have discussed on various occasions with some of you gentlemen and others.

"In 1956 the pharmaceutical industry mailed to each busy general practitioner something in excess of 4,000 pieces of literature. . . . The educational force of this mass of promotional material is bound to be tremendous. I am sure that for many physicians this is the primary source of new professional information. Much of this material is excellent and is educational in every sense of the word. Unfortunately, however, too much of it is less good than it should be—a fact to which I am sure all of you would agree.

"There is an alarming amount of pseudoscientific gobbledygook put out by some manufacturers. Fortunately this type of promotional material is usually self-evident and—I hasten and am happy to add—is not characteristic of the materials put out by the member firms of this association. On the other hand, what to me is quite as disturbing is to see good, solid scientific material quoted out of context—perhaps only a shade so but enough to color the interpretation of the reader and not give him all the facts in the case.

"There must be ever-mounting pressure within the industry to encourage all drug manufacturers to adopt the uniformly high standards now observed by so many of the major pharmaceutical firms. This is always a sign of a healthy, responsible industry. For, while we all recognize that pharmaceutical promotional materials can be a potent force in keeping physicians abreast of new developments, they inevitably will be suspect—and, consequently, discarded—if they are not good and deserving of trust.

. . .

"The method by which your industry is advancing in self-regulation . . . is impressive. In my recent contacts with the Food and Drug Administration, the many evidences of your enlightened self-interest are apparent daily.

"Recognition of the interdependence and the resultant productive cooperation between the Federal Government and the pharmaceutical industry has promoted a free exchange of new knowledge which has been to the distinct advantage of our national research effort."

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report, Issued May 24, 1957. —Seizure of 668 tons of unfit foods in April was reported by the Food and Drug Administration on May 24. Included were more than 500 tons of bulk wheat contaminated by rodents.

Other seizures in April involved eight lots of debased or substandard food and 12 lots of drugs. Five of the drug actions were against new products marketed without safety clearance, five were against substandard products and two were against misbranding with false and misleading claims.

During the month, also, false statements about foods and nutrition, used in house-to-house selling of vitamin products, were held to violate federal law in an opinion by the United States Court of Appeals at Boston. The court upheld the conviction of an individual and a corporation found guilty by a Boston jury in October, 1956, after a three-week trial. The individual was sentenced to a year in prison and the firm was fined $6,000.

A 20-page opinion by Chief Judge Calvert Magruder sustained the Food and Drug Administration's charges that literature and claims used in selling "natural" vitamin-mineral supplements constituted misbranding under the federal food and drug law. Specifically, the following claims, which were litigated in the trial, were held to be false and misleading:

(1) Nearly everyone in this country is suffering from malnutrition or in danger of such suffering.

(2) The soils of the United States are demineralized and depleted, thus producing non-nutritive food.

(3) Refining and processing of foods destroy their nutritive value.

(4) Practically all the illnesses and diseases of mankind are due to improper nutrition.

(5) The best way to treat, cure and prevent all the diseases of mankind would be by using the firm's vitamin-mineral products.

Listed as "deficiency diseases" in the sales literature were such ailments as diabetes, infantile paralysis, rheumatism, dementia praecox, tuberculosis and cancer.

Judge Magruder held that prospective purchasers "are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted, or who are susceptible to luridly painted

scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product."

Dietary-Food Labeling Requirements.—Regulations governing dietary foods have been amended to provide labeling requirements for foods which contain niacin or niacinamide. Daily requirements of the vitamin are stated to be as follows: five milligrams for a child less than six years old; 7.5 milligrams for a child six or more years old; and ten milligrams for an adult.

Earlier statements as to daily requirements for riboflavin have also been changed. Under the new amendment, requirements are: 0.6 milligram for an infant; 0.9 milligram for a child; and 1.2 milligrams for an adult.

The amendments are to become effective July 1, 1958, unless they are stayed in whole or in part by the filing of objections and request for a public hearing. Prior to July 1 of this year, objections may be filed with: Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue, S. W., Washington 25, D. C.

Inspection and Certification Fees to FDA.—Beginning June 1, 1957, the Administration became the recipient of certification fees for coal-tar colors, inspection fees for seafood and certification fees for drugs composed wholly or partly of insulin.

Food Standards—Canned Fruits and Orange Juice.—A petition has been filed by the National Canners Association, Washington, D. C., setting forth proposals for amendment of the definitions and standards of identity for canned fruits to provide for the use of artificially sweetened packing media (*22 Federal Register* 3733). The Commissioner of Food and Drugs filed an alternate proposal which would set up separate standards for artificially sweetened canned peaches, apricots, pears, cherries, fruit cocktail and figs. It is not contemplated that both proposals will be adopted, and interested parties may submit their views to the hearing clerk before June 27.

The National Association of Frozen Food Packers, also of Washington, has filed a petition proposing adoption of definitions and standards of identity for canned orange juice and industrial orange juice (for processing) (*22 Federal Register* 3893). The Commissioner has proposed the adoption of a definition and standard of identity for frozen concentrated orange juice and frozen sweetened concentrated orange juice (*22 Federal Register* 3894). Deadline for the filing of views and comments is July 4.

In the Public Health Service

Data on Polio Vaccine.—A total of 10 million cubic centimeters (doses) of new poliomyelitis vaccine was released during May, according to a Public Health Service summary. During the last week of the month, 2.5 million cc. were released.

On June 7, the service reported that inventories in the hands of manufacturers, druggists, physicians and health officers totaled about 9.2 million cc. for the week ending May 31. This was an increase of more than a million from the inventory—approximately 8 million cc.—that had been maintained for several weeks previous to that time.

The service collects the data on vaccine weekly to assist manufacturers in planning distribution and to aid local groups with vaccination programs. Data also go to the American Medical Association, the National Foundation for Infantile Paralysis, and the Association of State and Territorial Health Officers.

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Food·Drug·Cosmetic Law
Journal

AOAC Methods of Analysis

By W. B. WHITE

This Reprint from *Food Drug Cosmetic Law Quarterly* (now *Journal*), December, 1946, Directs Attention to "Machinery of the AOAC, . . . Grist It Turns Out and . . . How the End Product of Its Operations Serves the Cause of Justice"

Because of continued interest in the late Dr. White's paper, the *Journal* suggested to William Horwitz, secretary-treasurer of the Association of Official Agricultural Chemists, that consideration be given to bringing the article up to date by addition of interim changes. Together with Henry A. Lepper, AOAC's president, Mr. Horwitz studied the paper, and they decided that—in view of Dr. White's smooth and readable style—it would be most inappropriate to attempt to revise the paper. They did, however, furnish the footnotes bringing the factual material up to date. A few very minor changes were made and one entire section of the original article—on "Special Meaning of 'Tentative'," referring to methods of analysis—was deleted. It was felt that the section is no longer appropriate and, if included, would be misleading.

I OFFER NO APOLOGY for using the much-abused device of initials in the title, for *these* initials have an ancient and an honorable lineage. One might paraphrase Genesis by saying, "In the beginning there was the AOAC"—which letters, of course, stand for Association of Official Agricultural Chemists.

In that other genesis, emerging slowly from the primordial chaos of our mid-nineteenth-century heritage of English mercantilism,

Dr. White, Who Died in 1951, Was Chairman-Editor, Editorial Committee, *Journal of the A. O. A. C.*, and Chief of the Food Division in the Food and Drug Administration

caveat emptor and all the rest, it was early recognized that before adulteration and misrepresentation could be corrected there must be standards of reference. How could one tell, for example, whether an article was debased except by using an analytical method which would detect and, if possible, determine the amount of the debasing substance? Of course, the other fundamental standard of reference is also implicit in the problem of correcting adulteration; and this is posed by the question: "Just what are the metes and bounds of the article which is being debased?"

History of AOAC

When we think of adulteration nowadays, we are more likely to associate it with foods and drugs than with other members of that vague classification "agricultural products." The English, emerging earlier from the miasma of *laissez faire,* had in 1860 adopted a general law prohibiting the adulteration of *all* foods, but it was a whole generation later before the federal government here began to be concerned about foods and folks rather than fertilizers and feeds. So it was that the precursors of the AOAC, at their first meeting in May, 1880, were concerned simply and solely with analytical methods for determining phosphoric acid, nitrogen and potash in fertilizer—and mainly with phosphoric acid. Because it is typical of the broad problem of "standard methods," it is pertinent to quote the first three paragraphs of Dr. Wiley's excellent history of the AOAC which appears in Bulletin 57 of the United States Department of Agriculture Division (later Bureau) of Chemistry:

The condition of agricultural chemical work in the United States in 1880 was a peculiar one. The few chemists who were engaged in agricultural

research were acting in complete independence of each other in regard to methods of investigation and of research. Some of them were using the methods employed by German chemists, while others followed the instruction given by the French or English agricultural chemists. There was no unity of interest in the profession nor any common system of work. The condition of analytical work may be truly described as chaotic. The result of such condition is easily imagined. There was no standard of comparison or reference. Buyers and sellers were continually wrangling over analysis, which, made by different men following different methods, did not agree.

The sellers' chemists uniformly obtained higher results than the buyers', and thus the door to litigation was constantly open.

Strange as it may seem, the first steps toward correcting this pitiable condition did not come from the Department of Agriculture at Washington, but from the department of agriculture of one of the states. It was through the Hon. J. T. Henderson, Commissioner of Agriculture of Georgia, and at the instigation of Mr. H. J. Redding, now Director of the Georgia station, that the first step toward uniformity of action among agricultural chemists of the United States was taken.

These early meetings were known as conventions of agricultural commissioners and chemists, and commercial as well as governmental chemists not only attended, but also served on the committees. In August of the same year, they met in Boston as a section of the American Association for the Advancement of Science. At the third (and last) meeting of the precursor organization, held at Cincinnati in 1881, the commercial motive seems to have come into collision with the search for truth. At any rate, the Chemical and Fertilizer Exchange charged that "the Washington rules" (that is, the method for determining citrate-soluble phosphoric acid) did "crying injustice to the guano trade and to the farmer" by giving lower results than would a modified procedure.

"The rest is silence," as Hamlet said, until May, 1884, when Mr. Henderson called a conference in Atlanta. The idea, as he put it, was to adopt "a uniform and, if possible, a more generally satisfactory method of analysis in time to enable manufacturers, if necessary, to conform to the same in promulgating their work of and for the next season." The report of the organization committee contained this significant paragraph:

In answer to the objection that Unofficial Chemists would have no standing and no rights in the Association, Mr. Chazal, on behalf of the Committee, replied that it was the unanimous opinion of the Official Chemists that there were only two forms of association possible, one which should contain only Official Chemists and one where Official Chemists alone should have a vote, but in whose discussions and investigations any Agricultural Analytical Chemist

should have the right to participate; that the Official Chemists occupied the position of arbitrators, and could not consent to submit their methods to the votes of gentlemen without any legal responsibility.

That same year, in Philadelphia, the AOAC was born to begin a long and honorable career. At the second AOAC meeting in Washington on September 1, 1885, the United States Commissioner of Agriculture (the Department did not yet have cabinet rank) expressed the hope that the association "would not limit its attention to uniform methods of fertilizer analysis, but would extend its work to general chemical analysis." He commended its "special attention to the standard of purity of foods and methods of detecting adulteration." The first thin pamphlet titled *A. O. A. C. Methods of Analysis* was published in 1885, as Bulletin No. 7 of the Division of Chemistry, United States Department of Agriculture. It ran to 49 pages, and carries also the proceedings and the text of the first constitution, the first two articles of which read as follows:

I. This Association shall be known as the Association of Official Agricultural Chemists in the United States. Its object shall be to secure, as far as possible, uniformity in legislation with regard to the regulation of the sale of commercial fertilizers in the different states, and uniformity and accuracy in the methods and results of fertilizer analysis.

II. Analytical chemists, connected with departments of agriculture, state agricultural experiment stations and state boards, exercising an official fertilizer control, shall alone be eligible to membership; and one such representative from each of these institutions, when properly accredited, shall be entitled to a vote in the Association. All analytical chemists and others interested in the objects of the Association may attend its meetings and take part in its discussions, but shall have no vote in the Association.

Bulletin No. 12 of the above series (Uncle Sam paid the printing bills for the association in those halcyon days) was issued in 1886, and still contained nothing but fertilizer methods. But the next edition of *A. O. A. C. Methods* in 1887 (Bulletin No. 16) ran to 77 pages and included butter (nine methods), milk (ten methods, including alternates) and "cattle foods" (seven methods). It is true that some of them were about as simple as the celebrated method for making a statue—"take a block of marble and knock off all you don't want"—but there were others which have stood up pretty well, as far as broad general principles go, against the erosive forces of experience and cold, objective collaborative study. Bulletin 19 (1888) ran to 94 pages and bloomed forth with the following list of subject matter on its cover: "Commercial Fertilizers, Cattle Foods, Dairy Products and Fermented Liquors," thereby demonstrating that "man does not live

by bread alone." The same title is retained in Bulletin 24 (1890), which ran to 200 pages of methods and "proceedings." Sugar methods appeared, and they, too, got into the titles of Bulletins 28 and 31.

Time marched on, and the AOAC continued its healthy growth. At the sixteenth annual meeting in San Francisco, in 1899, something new had been added besides the extension of the subject matter to meat, cheese and insecticides. There appeared a report of the "Committee on Food Standards" (Dr. Wiley, chairman) appointed by the association in 1897. Because this report illustrates so clearly the intimate way in which food standards and standard methods for food analysis are enmeshed and even interwoven, it is of interest to quote a few sentences:

> From the subcommittee appointed by this committeee to consider the subject of classification and standards it is reported that Mr. A. L. Winton, of the Connecticut Station, has completed the chemical examination of a large series of imported spices sampled by him from the original packages; that Prof. F. W. Woll has completed the chemical examination of sixty samples of American and Canadian dairy and table salts, and has compelled a large number of analyses of these materials made by other chemists; that Dr. L. L. Van Slyke has gathered most of the material needful for the fixing of standards for American dairy products; that Dr. J. B. Lindsey, whose serious illness has prevented the formulation of his report, has gathered much of the data needful for the formulation of standards for grains and their products, including cattle foods; that Prof. M. A. Scovell reports the accumulation of most of the needful data for standards for sugars and related substances; that Prof. H. A. Huston reports that he has gathered together much of the needful evidence respecting substances artificially introduced with possible injury to health; that Prof. William Frear has made a considerable number of analyses of vinegars, and compiled data upon that subject.

The objective of such food standards is set forth thus in another portion of Chairman Wiley's report:

> It has been suggested by legal authorities in Congress that, in view of prospective early legislation for the establishing of national control of interstate commerce in foods and drugs, it is highly desirable that this association should, as promptly as existing information may make it possible to fix standards of strength and purity, prepare and publish such a set of standards to serve as a guide in the case of foods, just as the *United States Pharmacopoeia* does in the case of drugs, since reference to such standards in the course of the legislation indicated may prove desirable.

But the making of food standards is another story, and one with which the association soon ceased to concern itself. Let us dismiss it now with the observation that standards-making necessarily partook somewhat of the character of weaving a rope of sand until the Food, Drug, and Cosmetic Act of 1938 finally gave the Food and Drug Ad-

ministration a clear statutory mandate to promulgate such standards, which would have the full force and effect of law.

At this same meeting (1899), Dr. Wiley, as chairman of another committee, reported that Bulletin 46 was now revised and ready for issue. This was the first time that the *A. O. A. C. Methods* were unravelled from association proceedings and discussions. There were 24 pages devoted to fertilizers, four to foods in general (mainly "animal foods"), 15 to soluble carbohydrates (mainly sugars), 14 to dairy products, 14 to fermented and distilled liquors, seven to soils, three to "ashes" and three to tanning materials. In 1902 the food methods were issued by themselves as Bureau (vice "Division") of Chemistry Bulletin 65, and it was these *Provisional Methods* that the writer used as a textbook in a university course in food analysis given in 1904-1905. In 1907, all methods were combined in the historic Bulletin No. 107, under the caption *Official and Tentative Methods of Analysis of the A. O. A. C.*, running (in the 1912 revision) to 272 pages and covering 29 broad topics, 23 of which dealt directly or indirectly (colors, preservatives, etc.) with food for man.

In 1920, the AOAC struck out for itself, and published the first edition of its methods under the title *Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists.* [This book was in its sixth edition (1945) at the time of writing of this article, and ran to over 900 pages.[1] A printing of 9,000 copies [2] was made, and the book by then was going out to practically every civilized country in the world.] The preface to the second edition expresses so clearly the place of accurate analytical methods in the scientific and regulatory scheme of things that I can do no better than quote it here, together with the final sentence of Dr. Wiley's introduction to the same volume:

[1] The eighth edition (1955) runs to over 1,000 pages. The expansion between the sixth and eighth editions was confined to only 100 pages by the extensive use of abbreviations and cross-references and by elimination of almost all articles and many prepositions. A reviewer in *The Analyst*, the venerable British publication on analytical chemistry, cleverly commented on the style as follows: "The severely condensed style and system of abbreviation made necessary by the limits set to the size and weight of a book designed as a laboratory manual will be somewhat disconcerting to a reader who takes pleasure in words and their orderly arrangement. It is to be hoped that authors of chemical papers and books, with a less worthy motive and without the same insistent pressure on their space, will not subconsciously take this text as a model for their own writings; for the style, alas, is all too easily acquired, and this concd ext. of analytical chemistry contg max. of information in min. of space is calcd to be widely used by all chemists interested in the analysis and testing of agricultural materials, foods, drugs and allied substances."

[2] A printing of 12,000 was made of the eighth edition.

The Methods of the Association of Official Agricultural Chemists are unique in several respects. They are the outgrowth of continual critical collaborative trial or test participated in by a large number of workers and undertaken in order to establish the accuracy of analytical results. They are subjected to a scrutiny of phraseology to insure clarity, probably unequaled in developing any similar methods. They are formulated solely by responsible Federal and state officials acting together and thus are based on underlying principles of equity. The association has always encouraged to the utmost the cooperation of representatives of interested industries, but it has jealously reserved the final formulation of its methods to official chemists. Consequently, these methods have attained an enviable position in the fields of activity occupying the attention of the association and are accepted as authoritative in matters at issue before the courts, both Federal and state. . . . This revision of methods improves the value of the instruments in the hands of the seeker of new facts and the explanation of new laws.

1946 Scope and Methods of AOAC

It may not be amiss at this point to give some indication of the scope and method of operation of the association as it is now constituted [1946]. The size and distribution of the 1945 edition of *A. O. A. C. Methods* has already been mentioned. Its 932 pages carried imbedded in the text 76 cuts, diagrams and graphs, and an endless number of small reference and information tables; in the back of the book there are 83 pages of longer reference tables, covering 31 different topics.[3] There are 43 chapters which deal either with certain specific subject matter or with general subject matter such as enzymes, coloring matters, metals and spray residues, preservatives and other chemicals, vitamins, radioactivity, microbiological methods, microchemical methods (where only a minute sample is available for analysis), extraneous contaminating material in foods and drugs (identifiable mainly by microscopic appearance) and standard solutions. Twenty-two chapters cover the different broad classes of food products. There is a chapter on drugs that runs to 86 pages; there is a chapter each on cosmetics, caustic poisons, insecticides, plants, soils and naval stores; and there are two chapters each on fertilizers, etc., and on leathers, etc.[4] One can only say, with John Dryden: "Here is God's plenty."

At the meeting of the association which was held in the fall of 1944 (the World Wars three times broke the established custom of a yearly

[3] The corresponding figures for the eighth edition are: 1008 pages, 83 cuts and 93 pages of longer reference tables covering 32 different topics.

[4] The eighth edition contains 41 subject-matter chapters. The chapters on naval stores, leathers and tanning materials were eliminated in the seventh edition because of limited activity in these fields. The drug chapter, the longest in the book, runs to 103 pages. The former chapter on vitamins was renamed "Nutritional Adjuncts," a title intended to convey a recognition of the potentialities of nutritionally significant factors such as amino acids and antibiotics. A new chapter on spectrographic methods has been added.

meeting in Washington), there were about 400 working chemists present.[5] Some 140 of them were commercial chemists, who may and do collaborate on the study of methods but who cannot, under the constitution, vote, hold office or serve as general referees or on governing committees. The various federal agencies of a predominantly nonregulatory character were next, with 125 in attendance, followed by the Food and Drug Administration with 80 representatives, the state agricultural colleges and departments with 43, the state experiment stations with nine, and Canada with five.[6] Our Canadian neighbors have for years been faithful attendants and tireless workers on the floor and in committees. Perhaps this is the place to say that the full name of the organization is the Association of Official Agricultural Chemists of *North America*.

It is not necessary to go into the constitution and bylaws in any particular detail, except as they touch my main topic, to which most of what has been already said constitutes an introduction. While the function of the association (like that of the old Bureau of Chemistry, from whose loins it sprang) is a dual one—namely, part research and part regulatory—the emphasis in recent years has been more on those analytical methods which constitute good regulatory tools. The shift has been doubtlessly a reflection of the increasing complexity of agricultural research in recent years. The point needs no laboring for the average well-informed person. The number of branches on the tree of modern agricultural research are legion, and the necessary kit of scientific tools alone (leaving aside all of the economic, meteorological, sociological and ecological tools of agricultural research) is severalfold larger than the very extensive kit which has been found handy in the enforcement of the various regulatory laws. That is saying a great deal indeed, as will aready have been noted by a superficial glance at the chapter headings enumerated. Time was when a few reagents, a little standard glassware and a chemical balance were about all that were needed in a well-equipped regulatory laboratory. Let us turn to foods, which I happen to know most about, and take in only one small corner of that field as an illustration. In the race

[5] The total registration at the seventy-first meeting (1956), which also celebrated the fiftieth anniversary of the passage of the Food and Drugs Act of 1906, was 760, of whom 278 were commercial chemists.

[6] The corresponding figures for the 1956 meeting were: federal agencies of a predominantly nonregulatory character, 146; Food and Drug Administration, 160; state agricultural colleges, departments and experiment stations, 155; Canada, 18; and foreign, 3.

between man and insects for world domination, the history of modern drug synthesis is repeating itself. Like drugs, most insecticides are poisonous; indeed, we may say they are such by definition. When insecticides are used on food or feed crops they may leave residues which are harvested with the crop and eaten by the consumers, animal or human. This possibility is, of course, what makes accurate analytical methods for determining mere traces of the newer insecticides so important. A moment ago I used the synthetic-drug analogy; by this I meant that, just as a generation ago the synthetic organic chemist began building new drugs to the specifications of the doctor and the pharmacologist (as to therapeutic and other physiological effects), so that now this same organic chemist is building "pesticides" of various sorts to the specifications of the entomologist. The physiology of insects is even more obscure than that of humans, and the process of trial and error must therefore operate in even wider circles. It includes even more "cruel and unusual" synthetic organic chemicals, some of which are not intimately known even to their progenitors! Let us take the insecticide "666" as an example (reminiscent of Ehrlich's "606" of an earlier day). The compound as manufactured was known to have four different kinds of "666" in it in somewhat variable quantities, and these kinds are so near alike that they cannot be separated by any of the ordinary chemical means. The five-dollar chemical word for such close relatives is "stereoisomers." What matters is that we had first to employ an entirely new tool, as far as the AOAC methods were concerned, for separating these quadruplets in pure form so that we could make a start at developing a method for measuring each. Incidentally, only one of them is an effective insecticide. When we made this separation, we also found smaller amounts of two other entirely different compounds whose presence had not up to then been even suspected. This new separating tool has a five-dollar name too: chromatography. Having separated these quadruplets in pure form, they were then converted into dye-like substances by some rather intricate chemical reactions. This reduced the problem to one of handling a mere set of triplets—three different colors, showing three distinct curves in the visible part of the spectrum. Such a situation presents an almost insoluble problem, but by chasing these three dyes out into the invisible part of the spectrum (at the ultraviolet end) with another new tool, a miracle happened which we still find hard to believe. The three wandering absorption curves actually seemed to intersect at one point. This, if confirmed,

would mean that, at that point (wave length), all three of them could be measured at once. If the other tools had five-dollar names, this tool must be worth 25 in any market, for it is an ultraviolet photoelectric spectrophotometer.

With this illustration of the growing complexity of analytical methods, so necessary to match the increasing tempo and complexity of scientific progress, let us turn to the machinery of the AOAC, to the grist it turns out and to how the end product of its operations serves the cause of justice.

Enough has been said already to give a sufficient idea of the membership and aims of the AOAC. The officers consist of a president, a vice president and a secretary-treasurer, elected each year by the active members. "These officers," says the constitution, "the immediate past president, and three other active members to be elected by the Association, shall constitute the Executive Committee." A further quotation from the latter part of Article III and from two of the bylaws will suffice to show the genesis of analytical methods:[7]

With the concurrence of the Executive Committee, the president shall appoint a chairman and a committee of twelve other members, which shall be designated a Committee on Recommendations of Referees, one-third of the membership of which shall be appointed at intervals of two years to serve six years, the chairman to be appointed annually. The chairman shall assign the twelve members to subcommittees (A, B, C, and D) and shall assign to each subcommittee the reports and subjects which it shall consider. The President and Secretary shall appoint referees, from the active members of the Association, on the general subjects designated by the Committee on Recommendations of Referees, and shall also appoint associate referees on subjects designated by the Committee as supplemental to the general subjects assigned to referees. It shall be the duty of referees and associate referees:

1. To direct and conduct research on the methods and subjects assigned;

2. To prepare and distribute samples, and direct and conduct collaborative studies of methods; and

3. To present at the annual meeting the results of the work done and recommendations for methods to be based thereon.

By-Laws

. . .

5. Methods shall be adopted as "first action" and "official." No method shall be adopted by first action until it has received collaborative study and has been recommended by the appropriate referee at an annual meeting. No method shall be adopted as official except on recommendation of the appropriate referee at an annual meeting following the adoption of such method by first action. No change in an official method shall be adopted until after the changed method has received collaborative study and has been recommended by the appropriate

[7] The corresponding current Article III and Bylaws 5 and 6 have been substituted for those in effect in 1946. The major difference is the deletion of the class of methods formerly designated as "tentative."

referee at two annual meetings. No official method shall be repealed until such action has been recommended by the appropriate referee at two annual meetings. Such adoption, change, or repeal of methods shall become effective on the thirtieth day after publication of the record of such action in the *Journal* of the Association.

6. Upon the recommendation by the appropriate referee, the Association may adopt well established procedures for examination or treatment of a mechanical, microscopic, physical, chemical or other nature.

There are now [in 1946] 41 referees reporting to the four master committees (on "recommendations of referees"), and each referee is served by from one to 25 associates—some 250 in all.[8] These associates are served in turn by as many collaborators as have expressed interest in, and a desire to work on, the testing of a particular method, either as to its absolute value or by comparison with other methods, or with the same method in a somewhat different form.

However, as with all organizations, the important thing is not how they are set up on paper, but how they function. This goes to the spirit, which the Scriptures tell us "giveth light." And the spirit of science is a very luminous thing when, as here, it is permitted to operate with the utmost freedom. In a narrow sense, the AOAC may be the lengthened shadow of one man, Dr. Wiley; but in a broader and truer sense, the organization owes its spirit and its high scientific prestige to the simple fact that its members have no possible stake except the thrill of searching tirelessly and without remuneration for the very best analytical method which ingenuity can devise, whether it be a "pet" of some member, or a stranger without the gates. Let me here quote a sentence or two from the 1926 presidential address of one of our most honored members, Dr. C. A. Browne:

Without being swayed by the assertions of an ultraselfish commercialism we need always in the choice of our methods of analysis to consider the industrial point of view. After many years' experience as a commercial chemist, in a general as well as in a very specialized field, I would say that an analytical method of valuation which is acceptable to both sides of a transaction is usually about as just as any that can be devised. . . . That a method of analysis should not be improved because the change would involve an alteration in commercial practices is to shackle progress and to prohibit advancement. . . . In periods of scarcity, as during the recent war, when food and other commodities must be stretched to supply the deficiency, there is a necessary slackening in the strictness of regulatory control. The license thus permitted is then seized upon by unscrupulous interests as an excuse for long continued infractions of the law. At such times, when the morale is lowered, when public conscience is

[8] There are now 45 referees, each served by from one to 33 associates—some 302 in all. The largest field is "metals, other elements, and residues in foods," a reflection of the necessity for the development of methods of analysis for pesticide residues as a result of the passage of the Miller Amendment to the Federal Food, Drug, and Cosmetic Act.

dulled, when trade is arrogant, and when violation of the law is rampant, the control official should be fortified with every weapon at his command.

One of the many definitions of a scientist is "the only man who is glad when one of his pet theories or beliefs is shattered, because thereby knowledge is increased." It is this type of scientist who, I believe, without exception serves on the AOAC working committees. It is therefore no wonder that the words "AOAC method" are the equivalent among chemists of the word "sterling" on a piece of silver.

But let us take a hypothetical case of just how an AOAC method comes into being, and again it will be drawn from the subject matter with which I am most familiar. Suppose that the scientific or trade literature comes out with the proposal to put some chemical into food for some purpose or other which—to the proposer, at least—is a most laudable one. Suppose, further, that Food and Drug Administration inspectors actually encounter this use in one or more food manufacturing plants or perhaps state men make the discovery and communicate it to AOAC officials or to the Food and Drug Administration. Such a situation, of course, at once poses a problem in methods, sharpened perhaps by the fact that the exploiter of the chemical has no knowledge of its possible harmful effects on the consumer, being activated only by an all-too-common bland optimism on this vital issue. The problem thus is how accurately to determine the chemical (1) in the presence of all the ingredients which might be normal to the particular food and (2) in such body fluids as blood and urine, and perhaps in body tissues or organs as well (in case regulatory pharmacologists foresee the need of studies on the potential threat to consumer health). Here we are dealing with the need of a wholly new method rather than with the other situation of a need for a better, quicker, or more specific method to supplant or supplement an existing one; the AOAC machinery swings into action in much the same way in either case. The need is communicated at once to the general referee, together with all available information as to collateral methods or studies, if any, in the literature which promise to throw light on the problem. Perhaps the referee already has an associate referee who has been assigned the particular subject matter by his own agency because of his knowledge, interest and experience; if not, steps are taken by the AOAC to appoint such a man. In any case this man proceeds to devote as many of his waking hours to the problem as his job will permit—perhaps this is an important part of his job anyhow. He stays with it, using what assistance he can muster

among his colleagues and friends, until he has a method that gives good results in his hands. The method is now ready for collaborative study. The associate referee plans the study very carefully, probably discussing his plan with the general referee, testing the wording of the method on his assistants and perhaps doing a little intensive small-scale collaboration with them as experimental animals.

Out of all this comes a set of "cooked-up" samples to go out to the volunteer collaborators along with the method. If the associate referee is wise, he will advise them to do a little rehearsing on their own material so that they do not "come to the method cold," as chemists say. In the preparation of his samples he has made every effort (1) to get an absolutely uniform mixture of chemical and food, so that all portions sent out will be alike, (2) to insure safe arrival in a sound condition, (3) to include controls, or "blanks," alike in all respects to the "doped" sample except for the presence of the chemical, (4) to keep the collaborator absolutely in the dark as to which sample is which, (5) to load the food up with all the normal ingredients (such as seasonings, colorings, sweetenings, etc.) that it could ever be reasonably expected to contain and (6) to insure in every other way possible that the trial eliminates all variables except the well-known but little-understood "personal equation." As a rule, the collaborators are skilled along similar lines, and frequently interested "by first intention" with the particular problem in hand. Their reports and comments go back to the associate referee and his, in turn, to the general referee, together with whatever recommendations as to further study, modification, adoption, or other action by the association the findings seem to warrant. The general referee passes these on, with his own recommendation, to the appropriate one of the four great subject-matter subcommittees, which then considers all the data and makes *its* recommendation at the next annual AOAC meeting, to be accepted or rejected at the business session on the last of the three days of the meeting. During the first two days, the members of the appropriate subject matter section of the open meeting have listened to all of these reports and recommendations, and have had access to them if they wished, so that the whole proceeding represents democracy in its purest form. The point needs no laboring that any method which can pass through such an ordeal, and receive the accolade of "official final action," has well-demonstrated utility and reliability.[9]

[9] A section, "Special Meaning of Tentative," of the original has been deleted in this revision, since it is no longer applicable to the association's methods (cf. footnote 7).

Value of AOAC Methods in Court Cases

A final word about the value of AOAC methods in court cases: One could almost dismiss the matter with a wave of the hand accompanied by the mouth-filling legal phrase *"res ipsa loquitur,"* since many of the AOAC methods have been made an integral part of our standards of food identity, and these—as you know— have the full force and effect of law. I will name a few, omitting duplication:

Cacao products: fat (in chocolate), shell (in nibs)
Macaroni products: total solids
Flours: ash, protein, moisture, carbon dioxide (in self-rising flour)
Creams: fat
Evaporated milk: fat, total solids
Sweetened condensed milk: fat
Hard cheeses: moisture, fat
Soft cheeses: moisture, fat
Jams, jellies and fruit butters: soluble solids
Egg products: total solids
Tomato products: total solids, salt.

But whether an AOAC method is or is not "built into" an identity or other standard, it is extremely likely to be the method of choice in run-of-the-mine analytical work by both the manufacturing chemist and the regulatory chemist whenever the questions arise in twilight-zone cases: Is there just enough of a valuable constituent? Is there too much of an inert constituent? The wise old author of "Ecclesiastes" was right when he said: "Say not thou, What is the cause that the former days were better than these? for thou dost not enquire wisely concerning this." In former days, there was great to-do in court cases over which method was "best," which—as far as the court was concerned—amounted to "words, words, words." But today, in food or drug cases, it is more than likely that both trade and regulatory witnesses will have used identical methods and, when an appropriate one is available, "it's A. O. A. C. methods all the way."

The value which Commissioner Dunbar of the United States Food and Drug Administration places on AOAC methods found expression in a statement made by him to the field force in 1936. This was, of course, before the present Act became law, but it is equally applicable today:

To neglect the A. O. A. C. is to adopt the philosophy of the passenger who said: "Let it sink, it ain't our ship." In a very real sense, it is our ship. A. O. A. C. methods are the Law and the Prophets as far as Food and Drugs Act enforcement is concerned. They are to be used unless we have better ones, in which case the better ones are generally adopted by the Association as a matter of course. The improvement of existing Association methods before they are subjected to devastating court attack is a matter of real concern to us. Accurate and suitable analytical methods are so fundamental to a precise knowledge of the composition of normal products that they constitute the bottleneck in the control of adulteration and misbranding. Further, analytical methods for control work are subject to certain restrictions under which the "pure" scientist does not labor. In general, they must combine accuracy with extreme rapidity, and further, if it is humanly possible, they must employ the usual tools of the craft rather than call for special apparatus of a Goldberg character.

In a very real sense, one may say that AOAC methods, when applicable, are the Supreme Court of the analytical world. This assurance of a rock in the weary land of opinion evidence assures the manufacturer who uses adequate control methods, that if he will listen to what the methods tell him he can be sure that he will not run foul of any regulatory agency as far as the particular constituent he is measuring is concerned. Both parties are speaking a common language, to their great mutual advantage and peace of mind.

I mentioned earlier, but only briefly, the importance of wording chemical methods so clearly that even the intelligent greenhorn should not go astray. Analytical methods are analogous to cookbook recipes, but I venture to assert that the drafting of the AOAC methods is, in general, superior. Fortunately, the problem is not quite as difficult as with legal drafting, though even here the analogy is closer than it seems—and each has its own vocabulary of jargon. It is not enough to write so that one is understood; one must attempt that most difficult thing, to write so that one cannot possibly be misunderstood. As in politics, much heated discussion—and much recrimination, too—has its origin in the faulty drafting of a sound method. Like the Greek philosophers, we should "define our terms" before the discussion and the recrimination start.

Perhaps it is not too optimistic to express, in closing, my strong conviction that AOAC methods have made their own modest contribution to the current, and most laudable, streamlining of legal procedure by materially narrowing the issues in those actions in which the methods are a factor. **[The End]**

THE CONSUMER

Looks at Chemicals in Our Food

MY TOPIC is a timely one. There is a serious demand from consumers for information about chemical food additives and there is a disturbing lack of knowledge about the subject.

First, let us reach a common understanding about what we are discussing—the chemicals that appear in food. Chemicals are not new and unusual components of food. All food from table salt to complex proteins is composed of chemicals. But there are some chemicals in use today that were not known a few years ago. They cause the most concern.

The problem is not new. The misuse of chemicals in food was responsible in part for the enactment of the Pure Food and Drugs Act in 1906.

You may ask: "Well, if we are dealing with an old problem, why is there so much concern? Why not enforce the law and let the chips fall where they may?" The answer is that the law is not adequate to cope with the problem we face today. The original Food and Drugs Act of 1906 declared that food would be adulterated if "it contains any added poisonous or other added deleterious ingredient which may render such article injurious to health." Under it, our power to keep poisons out of food was severely limited because the government had the obligation of proving that a food containing an added poison might be harmful to health. Under that law each food was considered alone; if it did not contain sufficient added poison to render it injurious to health, we were powerless to act.

However, the total intake of poison by a consumer could not be controlled on a single-product basis. For example, if each of three

By GEORGE P. LARRICK

The United States Commissioner of Food and Drugs Read His Paper at the Third Annual Conference, Council on Consumer Information, at St. Louis, Missouri, on April 5, 1957

items of food contained one third of the amount of poison required to make it injurious, each would have been legal under the 1906 law, but the consumer who was unfortunate enough to eat these three items at a single meal might have been injured.

The Federal Food, Drug, and Cosmetic Act of 1938 attempted to remedy this by forbidding the addition of any poisonous or deleterious substance to any food except where it is required or cannot be avoided, in which event the Secretary of Health, Education, and Welfare shall establish, by regulation, the quantity that may be present without hazard to the public health.*

Why 1938 Act Doesn't Provide Solution

This doesn't solve the problem. It forbids the addition to food of any substance known to be poisonous or deleterious, leaving uncontrolled the addition of chemicals that have not been tested enough to show whether they are poisonous.

The present law permits untested or inadequately tested chemicals to enter the food supply. If the manufacturer who chooses to use new chemicals decides that he does not care to conduct adequate toxicity tests, the burden of determining whether the new chemicals should be in food then falls upon someone else—ordinarily upon the Food and Drug Administration. But we do not have the facilities to conduct independent tests on even a small fraction of the new compounds being proposed for food use. If we did have the facilities and conducted the tests, the law still would permit untested materials to be used in

* Sections 402(a) and 406(a).

food during the time they are under investigation. The safety testing of a chemical additive ordinarily requires a minimum of two years and often it takes longer.

I am not critical of the food industry in general. Most manufacturers recognize the great responsibility they have to the consuming public and do test new ingredients before adding them to food. They declare the presence of the additive on the label as required by law. A few of them advise consumers of the reason for using the additive and of the benefits resulting from its use.

Irresponsible Few

There are, however, some who have used chemicals without adequate testing. They try to hide the facts by declaring them inconspicuously and in vague terms. Sometimes they bring pressure to try to get the government to agree that they may label their products without showing the presence of the chemicals at all. In the past few months we have had to resist pressures of this type from segments of the food and chemical industries not wishing to declare the presence of a preservative in common use.

Granting that some consumers are opposed to any kind of additives, it is certainly no solution to conceal their use. The experience of the past 50 years has shown that manufacturers are better off and promote greater confidence on the part of consumers by being frank and truthful about their products.

Delaney Committee Sounds Warning

The need for better control was brought to public attention in 1951 and 1952 by the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics—the Delaney Committee. It pointed out that the number of chemicals entering the food supply of the Nation had increased tremendously in the previous decade. It concluded that in some instances chemicals had been utilized in and on the food supply of the Nation without adequate and sufficient testing of their possible long-range injurious effects; that the public is entitled to greater protection with respect to foods it must necessarily consume; and that such protection is not afforded by the existing legislation, under which the government may take no action until after the food has been placed on the market and injury may have occurred. Other responsible groups have considered the problem of making a

reasonable determination of the safety of food additives and have concluded that it needs to be faced now.

We have had some very narrow escapes because of the use of additives that had no place in food. It is inconceivable that this country should continue to expose itself indefinitely to the risks inherent in the present scheme of food control.

If new chemicals cause so much concern, why use them? Why not forbid the addition of any new chemical to the food supply?

We are not in a static society. No one is self-sufficient today. The change from an agricultural economy to an industrial economy requires city-dwellers to get food from distant areas. Even the farm family gets groceries from the supermarket. It is necessary to grow, process and package food so that it can be transported for thousands of miles and remain in good condition during extended storage.

When food chemists take foods like soybeans or peanuts and make from them a long list of other foods and food materials such as salad oils, shortenings and emulsifiers, this contributes to the well-being of the Nation. The wonderful variety of fruits and vegetables that are in supermarkets today would not be there at all were it not for the sprays and dusts that growers now use to combat insects, weeds, plant diseases, and other pests. Chemical agents are used for a great variety of other useful purposes, such as preserving, bleaching, prevention of caking, lubricating, thickening, flavoring and coloring.

Change in Homemakers' Buying Pattern

Today, approximately 22 million women are employed outside of their homes. It is a great help to them to be able to buy prepared foods that are ready to eat with a minimum of attention in the kitchen. Many of these foods in large part owe their existence to the use of newer chemical additives.

I am reminded of a remark a mother made to her six-year-old son in a supermarket. As he reached for a gaily colored package of food, she said: "No, Johnny, dŏn't get that. We'd have to cook it."

We think it would be improper to block the progress that is made possible by the safe, useful employment of chemical additives. How, then, can we foster progress and safeguard the public health?

Surely, the law should require adequate testing of a chemical before it is employed commercially in food. The test results should be

submitted to the government, and the chemical should not be used until the government—acting for all the people—agrees that it is safe for the proposed use.

In one form or another, these principles for safeguarding the food supply are being proposed to the present Congress. Several bills to amend the Federal Food, Drug, and Cosmetic Act are now before that body.

However, a new law will not solve all of the problems. Laws are not perfect. Some of the decisions made in good faith by the administrators of the law will turn out to be less than ideal. When improved scientific procedures reveal new facts, decisions may have to be changed. But if we have the best law it is possible to secure, if we give it the best administration possible, if we use the best scientific evidence available and if the administrators of the law are willing to consider new scientific facts as they become available and to make changes when necessary, we will safeguard the public health while securing the benefits of modern technology.

Immediate Problems Summed Up

There are some immediate problems with respect to chemical additives that may interest you:

There are many groups in this country with unorthodox ideas about food and about the proper method of obtaining wholesome food. Unscrupulous promoters spread these ideas and then cash in by offering vitamin and mineral products as cure-alls for every kind of human ailment. They are beginning to offer concerted opposition to any effort to require their claims to adhere to recognized scientific facts. We have recently prosecuted successfully two of the major peddlers of nutritional quackery. We have an injunction against a third. These, and others with related ideas, are banding together to fight the Food and Drug Administration and effective law enforcement. They attempt to smear the responsible scientists who make good food protection possible. We need your help in support of good law enforcement and in the education of consumers to the tactics being employed by militant food faddists.

There is considerable public concern about cancer-producing substances. Last August in Rome, Italy, there was an international conference on cancer. Some of the comments made there to scientists and for scientists were reported by the press and publicized widely in this

country. They were interpreted as indicating that many cancer-producing materials are being added to the food supply. The general apprehension was not allayed by several statements recently inserted in the *Congressional Record*.

I would like to emphasize that the Food and Drug Administration does not know of any evidence that our food supply or any individual food being distributed in this country produces cancer when it is eaten. If we had such evidence we could and would take immediate action to remove the food from the market under the present law.

Last December, the Food Protection Committee of the National Research Council issued a "Statement on What we Know About Possible Relationships Between Cancer and Food Additives." It is significant that it does not use the alarmist approach.

What about coal-tar colors in foods? Soon after the 1938 law was passed, we established—as authorized by the law—a list of coal-tar colors which, according to the best scientific evidence then available, were absolutely harmless. In the years that followed, the science of pharmacology made great progress. When improved techniques were applied to these materials, we found that some of the colors formerly considered harmless could produce adverse effects when fed to test animals in very high dosage. In some instances colors were used in foods in a concentration far greater than normal, and the food so treated caused stomach upsets. Our conclusion is that these colors are not harmful to man when used in a reasonable concentration in food, but they certainly do not meet the requirement of the law that they must be "harmless." We have therefore removed two orange colors and a red color from the list eligible for certification, and we are in the process of removing four yellows.

Some people have misinterpreted this action. They have charged that the coal-tar colors are capable of causing cancer because one of the intermediates used in the manufacture of some of the food dyes is recognized as capable of causing cancer. We do not know of any evidence that any coal-tar color now permitted in food or any of the three colors recently removed from the list of permitted colors is capable of causing cancer when added to man's food supply. We do not agree that chemicals made from a harmful starting material must themselves be harmful. It is well known, for example, that ordinary table salt (sodium chloride) is composed of two very toxic components—sodium and chlorine—either of which could cause serious effects, if not death, if fed alone to man.

Antibiotics and Food Products

Antibiotics have been proposed as additives to preserve food. We do not know enough yet about the effect on man of long-term consumption of significant quantities of antibiotics to sanction their widespread addition to the food supply. We have established tolerances for two antibiotics in uncooked poultry because poultry is always cooked before it is eaten and because the evidence in our possession shows clearly that no significant residue remains in the cooked bird when the amount of antibiotic in the uncooked bird is within the tolerance level.

Preparations containing penicillin are used to treat dairy cows that have an udder infection called mastitis. To keep the drug out of market milk we required the products to be labeled with a warning that the milk should be discarded for the first three days after treatment. But the dosage per treatment has gradually increased from less than 100,000 units of penicillin a few years ago to as much as 1½ million units, and the precautions originally deemed adequate are not sufficient now. There are minute quantities of penicillin in a significant percentage of today's market milk.

A number of medical experts whom we have consulted are concerned about the situation, although they are not sure than an imminent public-health hazard has been demonstrated. We are seeking means of getting penicillin out of milk. We have asked the United States Department of Agriculture to cooperate with us in a very broad educational campaign designed to acquaint dairymen with the steps they must follow to produce clean milk free of penicillin and we have published a proposed change in the regulations that would limit the amount of penicillin in a mastitis preparation to 100,000 units per dose.

There is considerable opposition to this last proposal. Many veterinarians and dairymen do not want to have the amount of penicillin limited. We have not yet decided what final action to take, but I can assure you that the decision will be one that, in our judgment, will be designed to protect the public health.

Pesticide Residues in Milk

Another recent survey shows that some market milk contains measurable quantities of pesticide residues, principally residues of chlorinated hydrocarbons such as DDT. We have yet not established

any tolerance for any pesticide residues in milk. Milk containing the residues is illegal in interstate commerce.

The mentioned clean-milk program being sponsored by the Department of Agriculture is designed also to acquaint dairymen with the precautions they must observe to keep pesticides out of their milk. We do not think the situation here is critical. It deserves attention and is receiving it.

Protection of Public FDA's Prime Concern

Incidentally, we have some requests from chemical manufacturers right now for the establishment of tolerances for very small quantities of pesticides in milk. We have not reviewed the scientific data submitted to show the safety of these residues and do not know what action will be taken on these petitions. Again, we can assure you that the action will be that which in our opinion, based on sound scientific evidence, will protect the consuming public. We will be glad to receive scientific facts, from anyone who has them, concerning the safety of small amounts of pesticides in milk.

There are many other important problems in this field. For example, there is little doubt that as the peacetime use of atomic energy grows, food will be exposed to small amounts of radioactive waste products. We will have to determine what residues of these substances are without hazard and see that the food supply contains no more than these safe amounts. **[The End]**

• ANTIBIOTICS—SALES-COST INFORMATION •

According to a Federal Trade Commission release of May 22, questionnaires will be sent to the Nation's 18 manufacturers of antibiotics, seeking detailed information on sales and costs of individual "wonder drugs" for each firm during 1950-1956. The questionnaires represent the second phase of an investigation based upon a resolution adopted July 22, 1953. The first questionnaire went out in July of last year, to obtain information on production, patents, and other data relating to supplies, discount schedules, allowances, and various conditions of sale.

The 1957 questionnaires, which are to be filled out and returned by July 1, will ask for statements on principal development expenses for the 1950-1956 period. Other data requested will be as to investment and plant equipment, national-defense construction, purchases of antibiotics for resale, and classification of employees engaged in antibiotics work.

By QUENTIN H. WOOD

EFFECT OF A SUBSTANCE NA
ON THE IMPLIED WARRANTY OF

DURING THE PAST 20 YEARS the courts in a number of jurisdictions have had occasions to consider the question of whether the presence in food of a substance which is natural or indigenous to that particular food constitutes a breach of an implied warranty of fitness so as to give rise to a cause of action on the part of a purchaser who suffers an injury from the substance. It is believed that a survey of these decisions will be of interest to those who are involved in one way or another in product-liability cases.

Under the common law, the rule was that a vendor was not liable to his vendee for any defect of quality in chattels sold unless he had given an express warranty. There was an exception to this rule applicable to one engaged in the sale of food or drink; he was held to be under a public duty to sell articles that were wholesome. Blackstone stated, in *Commentaries*, Volume 3, page 165: "In contracts for provisions it is always implied that they are wholesome, and if they be not, the same remedy (damages for deceit) may be had." [1]

Section 15 of the uniform sales act, now adopted in thirty-three states, Alaska, the District of Columbia, Hawaii and the Panama Canal Zone, provides that there is no implied warranty or condition as to the quality or fitness for any particular purpose of goods supplied under a contract to sell or a sale, except as follows:

(1) Where the buyer, expressly or by implication, makes known to the seller the particular purpose for which the goods are required, and it appears that the buyer relies on the seller's skill or judgment (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be reasonably fit for such purpose.

Since the uniform sales act makes no special provision for warranty in sale of food, the distinction between the sale of food and other goods

[1] Williston on Sales (Revised Ed.) Vol. 1, p. 633, Sec. 241.

CE NATURAL TO A PRODUCT TY OF FITNESS

The Author, Member of the Legal Staff, Swift & Company, Chicago, Reviews Cases Determining Whether a Seller Will Be Held to a Standard of Perfection or Only to One of Reasonable Fitness, Where an Indigenous Substance Is Left in a Food Due to Practical Difficulties of Removal

has disappeared. However, circumstances may indicate the justifiable reliance on the skill and judgment of a seller of food which would not be so conclusive in the sale of other goods.[2]

For the purpose of this article it is assumed that there is an implied warranty of reasonable fitness for human consumption incident to the sale of the food involved, and our only consideration is whether such warranty was breached by the presence in the food of a substance natural to the original product and not removed therefrom in the process of preparing it for sale or consumption. We are not concerned here with cases where there is found to be an express warranty, such as a California case holding that a label, coupled with the representations made in newspaper advertising, constituted an express warranty that a can of "boned chicken" contained no bones.[3] There is obviously no liability incurred, whether an action is brought for breach of warranty or on a negligence theory, unless there is a legal defect in the food purchased.

In determining whether a food containing a substance which was natural to the original product and not removed therefrom is reasonably fit for human consumption, the great weight of authority is to the effect that the presence of such substance does not render the product unfit for human consumption since there is no obligation

[2] Work cited at footnote 1, at p. 636. Sec. 242a, citing *Rinaldi v. Mohican Company*, 225 N. Y. 70, 121 N. E. 471 (1918).

[3] *Lane v. C. A. Swanson & Sons*, CCH Food Drug Cosmetic Law Reports ¶ 22,395, 130 Cal. App. (2d) 210, 278 Pac. (2d) 723 (1955).

to furnish a perfect food and, even though the substance is present, the food is still reasonably fit for human consumption. As long as the substance contained in the food is natural to the food involved, the cases hold that as a matter of law the food is not rendered unfit for human consumption because of the presence of the substance.

Mix v. Ingersoll Candy Company

In the leading case of *Mix v. Ingersoll Candy Company*,[4] the action was based on an injury sustained due to the presence of a chicken bone in a chicken pie. The action was brought both on a negligence theory and for breach of warranty. The defendant demurred to the complaint, and the court sustained the demurrer and entered judgment for the defendant. In affirming the lower court's judgment, it was said:

> We prefer to rest our decision upon the broader ground that the facts stated in both counts of the complaint were insufficient on which to base an action no matter how the pleading was drawn. . . . Bearing in mind the exact wording of Section 1735 of the Civil Code whereby the implied warranty is imposed upon a restaurant keeper, is there an obligation imposed by the statute upon a restaurant keeper to furnish perfect food to his patrons at all hazards; that is to say, is his obligation that of an absolute insurer of his food? The answer, in our opinion, must be in the negative. The words of the code section are that the food furnished by a restaurant keeper shall be "reasonably" fit for such purpose—human consumption. It may well happen in many cases that the slightest deviation from perfection may result in the failure of the food to be reasonably fit for human consumption. On the other hand, we are of the opinion that in certain instances a deviation from perfection, particularly if it is of such a nature as in common knowledge could be reasonably anticipated and guarded against by a consumer, may not be such a defect as to result in the food being not reasonably fit for human consumption. The facts presented in the instant case, we think, present such a situation. We have examined a great many cases dealing with the question of the liability of restaurant keepers which arose out of the serving of food which was held to be unfit for human consumption and we have failed to find a single case in which the facts are similar to the instant case, or in which a court has extended the liability based upon an implied warranty of a restaurant keeper to cover the presence in food of bones which are natural to the type of meat served.

Decision as to Reasonable Fitness

The court stated that it was not necessary to take judicial notice of the fact that chicken pies usually contain chicken bones. It was held to be sufficient that it may be said that as a matter of common knowledge chicken pies occasionally contain chicken bones. It was the opinion of the court that despite the fact that a chicken bone may occasionally be encountered in a chicken pie, the pie is reasonably fit for human consumption in the absence of some further defect.

[4] 6 Cal. (2d) 674, 59 Pac. (2d) 144 (1936).

The court went on to say:

> Bones which are natural to the type of meat served cannot legitimately be called a foreign substance, and a consumer who eats meat dishes ought to anticipate and be on his guard against the presence of such bones.

In a later California case,[5] the plaintiff had sustained an injury caused by a piece of bone in a "special plate" of roast turkey with dressing and vegetables. Bone was contained in the dressing, but the court stated that the turkey and dressing constituted one dish in which there was no substance not "natural to the type of meat served," and thus the product was reasonably fit for human consumption. The *Mix* case was cited as establishing the criterion upon which liability is determined as being whether the object causing the injury is "foreign" to the dish served. The California law is thus clear that the presence of a substance natural to the product involved does not render said product unfit for human consumption. In these cases there was no foreign substance contained in the products; a consumer is expected to anticipate and guard against any substance natural to the product which might possibly cause him any injuries.

The above cases represent the weight of authority as regards the interpretation of the statutory provision that goods shall be "reasonably fit for such purpose." The cases clearly hold that a product cannot be considered unfit for human consumption merely because it contains a substance which is natural thereto and which was not removed in the processing of the product. The decisions indicate that such a substance is not considered a foreign substance and, therefore, there is no breach of the implied warranty of a reasonable fitness for the purpose of human consumption.

Norris v. Pig'n Whistle Sandwich Shop

In a Georgia case decided in 1949, where the plaintiff attempted to recover damages for an injury sustained by swallowing a particle of bone contained in a barbecued pork sandwich, a nonsuit was entered.[6] The action was based upon the alleged negligence of the defendant in failing to discover the presence of a piece of bone in the meat. On appeal, this judgment was affirmed. The court there stated that the defendant did not have a duty to furnish an absolutely perfect product and, since a particle of bone in a food prepared from meat is something which one might ordinarily expect to find in the food,

[5] *Silva v. F. W. Woolworth Company*, 28 Cal. App. (2d) 649, 83 Pac. (2d) 76 (1938).

[6] *Norris v. Pig'n Whistle Sandwich Shop*, CCH Food Drug Cosmetic Law Reports ¶ 85,117, 53 S. E. (2d) 718 (Ga. App., 1949).

its presence did not authorize an inference of negligence in preparing the food.

The court also found that the Georgia food and drug law defining adulteration was not violated, since the bone was indigenous to the animal from which the food was derived. The barbecued pork sandwich thus contained nothing which would render it unfit for food.

Davison-Paxon Company v. Archer

In a recent case, the Georgia Court of Appeals recognized the principle of the *Norris* case that a defendant would not be liable for injuries caused by a substance natural to the dish eaten, but would not go so far as to say that the plaintiff was required to prove that "the hard, sharp substance" which was contained in creamed turkey was not a substance natural to the food eaten.[7] This was held to be a defensive matter and not a matter which the plaintiff was required to prove.

Subsequent to the *Mix* and *Silva* cases there have been a number of cases which have followed their reasoning and denied any recovery by the plaintiff. In *Brown v. Nebiker et al.*,[8] the plaintiff, as administratrix of the estate of one Robert E. Brown, sought to recover for an injury sustained by Brown resulting from the presence of a sliver of bone in a pork chop. The court held that there was no obligation imposed upon the restaurant keeper to furnish perfect food, but only to furnish food which was reasonably fit for human consumption. In the words of the court: "One who eats pork chops . . . or the type of meat that bones are natural to, ought to anticipate and be on his guard against the presence of bones, which he knows will be there." The lower court's action in directing a verdict was affirmed.

In the foregoing cases, the substance was a thing natural to the original product. The rule is, of course, different if the substance is one not natural to the product involved. In the case of *Arnaud's Restaurant, Inc. v. Cotter*,[9] the action was for damages for personal injuries resulting from the ingestion of a piece of crab shell in pompano en papillote served by the defendant. The court, in affirming the judgment for the plaintiff, stated that the principle that a customer who eats meat dishes ought to anticipate the presence of bones which are natural to the type of meat served, and cannot hold the restaurant keeper liable for injury occurring as a result of the presence of such

[7] *Davison-Paxon Company v. Archer*, 91 Ga. App. 131, 85 S. E. (2d) 182 (1954).

[8] 229 Iowa 1223, 296 N. W. 366 (1941).

[9] 212 F. (2d) 883 (1954).

bone, is supported by a number of authorities, but was not applicable in this case. The court said that those cases were based upon the proposition that a bone natural to the meat which is served is not a substance foreign to that particular dish. However, in this case crabmeat was not used in the preparation of pompano en papillote and, therefore, the piece of crab shell was a foreign substance in that dish. The United States Supreme Court denied a writ of certiorari in this case.[10]

In an interesting case decided in 1955,[11] the plaintiff was served a dish known as "hot barquette of seafood mornay," which contained several different kinds of fish. While eating this dish, a fish bone lodged in the plaintiff's throat, requiring hospitalization and the aid of a physician to remove the bone. The dinner had been arranged by a third person, and Mr. Shapiro did not know what the dish was that was served to him. The court nevertheless held that the fish bone was natural to the dish served and, under the rule of the *Mix* case, the person who ordered the meal and knew what was served could not recover for any injury caused by a fish bone, and the restaurant keeper had no greater duty to the plaintiff than he had to the person who arranged for the meal. The court, consequently, entered judgment for the defendant.

Goodwin v. Country Club of Peoria

An Illinois appellate court has followed the rule of the *Mix* case and found it to be sound and well reasoned.[12] This was an action by the administrator of Mrs. Goodwin's estate. She had died as the result of an injury to her esophagus caused by a turkey bone contained in "creamed chicken" which was actually made from turkey. The trial resulted in a jury verdict for the plaintiff. On appeal, it was urged upon the court that the presence of a bone which is natural to the type of meat served is not a breach of an implied warranty that the food is reasonably fit for human consumption. The court accepted this reasoning and reversed the judgment.

In another case decided in 1955, it was held by the United States Court of Appeals that the plaintiff had no right to recover if the injury complained of was inflicted by a whole chicken bone contained in canned chicken fricassee because it is undisputed that bones are

[10] 348 U. S. 915, 99 L. Ed. 717, 75 S. Ct. 295.

[11] *Shapiro v. Hotel Statler Corporation*, 132 F. Supp. 891.

[12] *Goodwin v. Country Club of Peoria*, 323 Ill. App. 1, 54 N. E. (2d) 612 (1944).

normally left in chicken as cut up for fricassee.[13] It is interesting to note that the court took judicial notice of the fact that a chicken contains many small bones less than an inch in length. The court said: "The bony structure includes sixteen distinct cervical vertebra." It cited Hyman, *Comparative Vertebrate Anatomy* (Second Edition, 1942).

When Fitness Is Jury Question

The aforementioned cases were decided on a question of law and it was held that, as a matter of law, the presence of a substance natural to a product did not render that particular product "unfit for human consumption," as that term is used in the implied-warranty provisions of the uniform sales act.

No case has been found where the presence in a food of a substance which was natural to that food has been held to constitute a breach of implied warranty of fitness as a matter of law. Only three cases have been found where the question of reasonable fitness was left to the jury.

Bonenberger v. Pittsburgh Mercantile Company

In *Bonenberger v. Pittsburgh Mercantile Company*,[14] the plaintiff purchased oysters in a sealed container. She emptied the can of oysters into a pan of milk to prepare oyster stew. In tasting the broth she swallowed a sharp oyster shell which injured her esophagus. She thereafter filed a lawsuit based upon the breach of an implied warranty of fitness. The majority held that it was a question for the jury as to whether the product was reasonably fit for human consumption. The court cited no authority for extending liability upon an implied warranty to a case such as this and I know of no such authority. The dissenting judge, who was joined by the chief justice, argued that the oyster shell was natural to the product and the likelihood of its presence, arising from practical difficulties of separation in the processing for consumption, is a matter of common knowledge; the presence of the shell, therefore, breached no implied warranty of fitness.

When the courts speak of reasonable expectation in connection with substances natural to the product, they appear to be saying that the two things are interdependent, that is if the substance is natural to the product the consumer should expect that it may be present and he should be on guard against that possibility. Experience

[13] *Wieland v. C. A. Swanson & Sons*, CCH Food Drug Cosmetic Law Reports ¶ 22,413, 223 F. (2d) 26.

[14] 345 Pa. 559, 28 Atl. (2d) 913 (1942).

supports this reasoning, since we all are somewhat cautious, in eating foods such as fish, to guard against swallowing any bones which might be present and which might cause injury to us.

An interesting case involving natural salt crystals which formed in canned crabmeat after the canning process had occurred arose in New York.[15] In this case the plaintiff was injured by these natural salt crystals and brought action for damages against the defendant. Judgment was rendered in favor of the plaintiff for the injuries she sustained. On appeal, this judgment was sustained, but the decision gives very little guidance on the problem under consideration since the court assumed without discussion that the presence of the salt crystals constituted a breach of implied warranty of fitness. There seemed to be a preoccupation with the question of whether the husband could recover on a breach-of-warranty theory for consequential damages sustained by him for "loss of his wife's services, loss of society, and expense incurred for medical attendance and treatment," which question was answered in the negative. The court, however, did say that the presence of the salt crystals did not constitute an adulteration of the product under the state agriculture-and-markets law. It is suggested that in light of the great weight of authority it should have been held in this case—and probably would have been so held had the question been considered—that the presence of the salt crystals did not render the product unfit for human consumption. However, a lower New York court has interpreted this decision as holding that even though the salt crystals are natural to the product, they are legally deleterious.[16] I do not believe that the *Gimenez* case required this holding, since the question was not argued to the court.

Bonker v. Ingersoll Products Corporation

One other case has been found where the plaintiff was allowed to recover for an injury resulting from the presence in a food of a substance natural thereto.[17] This case involved "boneless chicken fricassee," and the plaintiff was injured by swallowing a piece of bone. No argument was made to the court as to whether there was a breach of warranty because the defendant had relied entirely upon the defense that notice of the injury was not given "within reasonable time after breach." In addition, there would, of course, be a serious question

[15] *Gimenez v. The Great A & P Tea Company*, 264 N. Y. 390, 191 N. E. 27 (1934).
[16] *O'Hare v. Petersen*, 174 Misc. 481, 21 N. Y. S. (2d) 487 (1940).
[17] *Bonker v. Ingersoll Products Corporation*, CCH Food Drug Cosmetic Law Reports ¶ 22,414, 132 F. Supp. 5 (1955).

in this case as to whether there existed an express warranty, since the product was sold as being boneless.

In addition to the bone cases which have been herein referred to, there is an unreported Massachusetts case holding that there was no breach of warranty due to the presence of a cherry pit in a cherry pie,[18] which was referred to by the Court in the *Mix* case when it was stated:

> Certainly no liability would attach to a restaurant keeper for the serving of a T-bone steak, or a beef stew, which contained a bone natural to the type of meat served, or if a fish dish should contain a fish bone, or if a cherry pie should contain a cherry stone—although it be admitted that an ideal cherry pie would be stoneless.

Clear-Cut Decisional Trend

From the foregoing survey it is clear that the courts are interpreting literally the "reasonably fit for such purpose" phrase of the implied-warranty provision in the uniform sales act. A seller will not be held to a standard of perfection, but only to a standard of reasonable fitness. If an indigenous substance is left in a product because of the practical difficulties of removal in the processing for consumption, the purchaser is required to anticipate its presence and guard against any injury therefrom. Because of this and the fact that there is no foreign matter involved, the product is deemed reasonably fit for human consumption. There is, therefore, in these cases no breach of the implied warranty of fitness. This interpretation of the law is well reasoned and refreshing to observe at a time when there appears to be a trend in some jurisdictions toward absolute liability in the food-products field. **[The End]**

CHAIN STORE OPERATING MEAT-PACKING PLANT —JURISDICTION

A complaint charging a grocery chain with inducing favored treatment from its suppliers has been dismissed by a Federal Trade Commission hearing examiner, who ruled that the chain store, which also operates a meat-packing plant, is a "packer" under the terms of the Packers and Stockyards Act and is, therefore, under the exclusive jurisdiction of the Secretary of Agriculture. The Commission's complaint had been issued in November, 1955, and amended last March.

The Packers and Stockyards Act, the examiner said, is "clear and unambiguous" and provides that the FTC "shall have no power or jurisdiction so far as relating to any matter which by this Act is made subject to the jurisdiction of the Secretary . . . ." (Released April 18, 1957.)—CCH TRADE REGULATION REPORTS ¶ 26,454.

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[18] *Marnelos v. Anastasovites* (DC Springfield, Mass., App. Div., March 9, 1933).

MEDICATED FEEDS AND THE FEDERAL LAW

By RALPH F. KNEELAND, JR.

The Author, Who Has Been with the Food and Drug Administration Since 1935, Is Assistant to the Director of Its Bureau of Enforcement. His Paper Is Derived from a Speech Before the Colorado Grain, Milling and Feed Dealers Association, Which Met at Denver on February 26

MR. CHAIRMAN, MEMBERS, and Guests of the Association: When Mr. Larrick was asked by your chairman, Mr. Covington, to speak to your group on formula feeds he was disappointed at being unable to accept the invitation. I, however, was every pleased when he asked that I take over this assignment to discuss with you some of our mutual problems.

For perhaps a considerable number of your members, the Food and Drug Administration and the requirements of the Federal Food, Drug, and Cosmetic Act have only recently assumed some importance in your day-by-day operations. Traditionally, the state control officials have assumed a major responsibility in the regulation of animal feeds. During this long era when animal feeds were strictly foods for animals, there was little reason for the federal government to expand its activities in the regulation of animal feeds. While maintaining close liaison with the state officials throughout the years, the federal control officials have remained in the background. With state laws designed specifically to deal with animal feeds, enforced by capable officials with excellent facilities, it was logical for the federal government to leave responsibility in the hands of the states in this area.

Until a relatively few years ago, regulatory activities under the Federal Food, Drug, and Cosmetic Act were largely limited to various rare cases where the broader jurisdiction of the federal law was needed to supplement or implement the work of some state

official but, like most other things today, life has become more complex for both the feed manufacturer and for the state and federal feed-control officials. Scientific developments in the production of livestock and poultry and the advent of medicated feeds have brought about numerous changes in the pattern of feed control, as they have in the production of formula feeds.

Statement by Commissioner Larrick

In a word of welcome at a symposium on medicated feeds held a little over a year ago in Washington, Commissioner George P. Larrick stated:

> This symposium is but one of many manifestations of the growing importance of medicated feeds. I should like, if I may, to take a minute to emphasize the national importance of medicated feeds. As all of you well know, they present numerous highly complex scientific and technical problems. There are also major economic considerations involved, not only for the manufacturers but for the farmer, the meat packer, and for the consumer. Some of these have not yet been fully answered. But over and above all of these, however, looms one paramount consideration. It must govern your actions and it will govern ours. It is the basic concept of all food and drug legislation—the protection of the public.
>
> Medicated feeds cannot be viewed only in terms of their economic or medical effects on poultry, pork and beef. We, and you, must primarily be concerned with the question of whether or not the treated meat has any discernible adverse effects on the human consumer. Our nation's food supply is fundamental to our nation's health and therefore its strength. These are not matters to be taken lightly. On the contrary, these are matters demanding of our best scientific skills, our best educational efforts, and our best enforcement standards.

Mr. Larrick also stated:

> There has long been too much confusion in the minds of some concerning the role of enforcement officials and the regulated industries. Many still regard our relationship much as a game of cops and robbers. While legal enforcement actions and supporting investigatory procedures will probably always be needed, it nevertheless is becoming increasingly apparent that meetings and joint educational activities such as this go a long way toward providing an understanding of the problems, their solution, and a sound basis for voluntary cooperation and compliance. The latter is a major objective of the Food and Drug Administration and the Federal Food, Drug, and Cosmetic Act.

I am confident that I speak both for Commissioner Larrick and all the others in the Food and Drug Administration when I state that I believe you have a keen awareness of your responsibilities not only to the farmers whom you serve directly, but also to the public consuming the food the farmer produces.

As Mr. Larrick stated, we are not engaged in a game of cops and robbers. If my presence here at your meeting will in some small measure throw light on the policies and procedures that we

follow under the Federal Food, Drug, and Cosmetic Act, I am confident that the information will be welcomed and utilized by the vast majority of you here in striving for our mutual objective—better service to the public.

The chairman of your formula-feed committee, Mr. Covington, in a letter to me, wrote:

> While I realize and appreciate that the department regulations are not intended to be ambiguous, as an ex-government employee myself, I know that to the medium size and small formula feed manufacturer, it is sometimes difficult to always be in 100% compliance although it certainly is not the intention of at least 99% of these manufacturers to willfully violate any governmental regulations.

May I say on behalf of the Food and Drug Administration that our experience over the past 50 years confirms Mr. Covington's statement that the vast majority of firms are not only willing, but anxious to comply with the regulations, but that some violations do occur because of the lack of understanding of the legal requirements. We hope that we do not have too many ambiguous regulations under the federal law.

Application of 1938 Act to Animal Feeds and Drugs

As you all know, the Federal Food, Drug, and Cosmetic Act is not a specific feed law. "Food" is defined under the statute as meaning food for man and other animals. Drug provisions apply both to drugs intended for man and those for the treatment of other animals. In our interpretations of the provisions of this law, as they apply to medicated animal feeds, we have attempted to keep in mind, without violating any of the basic adulterations and provisions of the federal law, the different problems which exist in the production of feeds and drugs for animal use and those for human use.

At the last annual meeting of the American Feed Manufacturers Association in Chicago last May, Mr. Bradshaw Mintener, then Assistant Secretary of the Department of Health, Education, and Welfare, made a statement that very briefly sums up one of the most important reasons why we are much more active in the regulation of the feed business today than we were before the advent of medicated feeds. He stated:

> It has been recently said that feed manufacturers today are in the drug business. I would like to suggest that while you are in the *feed manufacturing* business, you are perhaps more importantly in the *food producing* business, meaning that which is consumed by human beings.

In making that statement, Mr. Mintener highlighted what we regard as one of our most important obligations under the Federal Food, Drug, and Cosmetic Act, namely, to insure the public of a safe and wholesome food supply. We believe you share our views as to the importance of this objective of the federal law.

Developments in Feed Industry in Recent Years

How has this brought about the closer relationship that now exists between your industry and the Food and Drug Administration? Let us stop briefly to look back at some of the developments in the feed industry during the past ten or 15 years. Up until the late 40's the use of animal feeds for the administration of preventive and treatment levels of drugs appeared only sporadically and to no significant extent. It was not until the development of sulfaquinoxaline that medicated feeds began to receive widespread publicity and public acceptance. The effect of poultry feeds containing sulfaquinoxaline in reducing losses from coccidiosis led to the rapid development of other drugs for the same and other disease conditions. Today, the list of drugs used to medicate feeds is impressive in length and includes various antibiotics, arsenicals, hormones, cadmium compounds and piperazine compounds, as well as many others. It is safe to predict that the use of medicated feeds will undoubtedly increase as new drugs are developed and their effectiveness in feeds demonstrated.

You who are in the feed-manufacturing business need not be told that many of these drugs are capable of producing profound physiological effects and other effects upon animals when present in only very small amounts in the rations. It was therefore quite logical that, with this development of medicated feeds, both federal and state feed-control officials should concern themselves with the effects of the practice on foods produced from animals treated with these new products as an additional regulatory obligation. In stating this, I do not mean to suggest in any way that the feed manufacturers or the suppliers of drugs used in medicated feeds also have not been alert to this phase of the matter.

We believe that there has been general recognition on the part of the feed-manufacturing industry and its drug suppliers that a conservative approach to these matters is essential, both from the standpoints of the public generally and of the industries themselves.

The Food and Drug Administration has vigorously employed the various provisions of the federal law to protect both industry and consumers from the potential consequences of unwise actions in this area. We have diligently tried to base our actions squarely on the law, which is designed to protect the consumer and to make our decisions reasonable, sound and scientific. We have been gratified with the response of your industry to revised practices in the labeling and clearance of products under the federal law, which to many were both new and cumbersome as compared to previously accepted practices.

Let us look at some of these procedures and regulations which you have had to face in more recent years under the federal law:

It has been necessary, under the statute, to consider medicated feeds as drugs because such products meet either of two of the several definitions for a drug. These two are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Into the first class falls the products that are used to prevent or treat animal diseases; in the second class, the products to which drugs are added to promote growth or otherwise affect the function of the animal. This classification of medicated feeds as drugs has made it necessary that these products bear a labeling as required for drugs under the law. These requirements include adequate indications and directions for use, adequate warnings against misuse, and label declarations clearly identifying the active drug ingredients of the products.

In addition to generally defining drugs, the statute also defines a "new drug" as "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof" or "any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." The other section of the law which has had a profound effect upon the feed-manufacturing business is that which deals specifically with the

class of products which are generally referred to as "certifiable antibiotics." It is these provisions of the law and the regulations issued under them, that determine what must be done in order to market a product that is in compliance with the federal Act.

If the product you desire to manufacture or distribute is neither a new drug nor one which contains a certifiable antibiotic, you are not required to go through any formalities with the Food and Drug Administration. There is no type of registration procedure that must be followed, but the statute does, of course, impose upon you the responsibility for compliance with its general terms if you distribute the product in interstate channels.

We, of course, are always glad to discuss, in correspondence or in person, our views with respect to the application of the law to such a product when sufficient facts are presented to do so. In general, this will mean the quantitative formula and the proposed labeling of a product.

It is in the case of medicated feeds which are classified as new drugs, or which contain certifiable antibiotics, that a feed manufacturer comes face to face with more detailed requirements and regulations.

The new-drug section of the federal law denies the channels of interstate commerce to a new drug unless the manufacturer or distributor holds an effective new-drug application for his specific product. Our correspondence indicates there does exist some misunderstanding that, under the new-drug provisions of the law, the Food and Drug Administration is approving some particular use of a medicated feed or dealing generally with a class of products. This is not the case. In considering a new-drug application, the Administration is evaluating the specific facts about a specific product of a manufacturer in the light of the statements made in his new-drug application. The Act itself spells out six different categories of information that must be included as a part of a new-drug application. All are important, but I wish to comment briefly on two.

One reads "full reports of investigations which have been made to show whether or not such drug is safe for use." Shortly after it became apparent that the use of medicated feeds in the production of poultry and livestock was to become a widespread practice, it became necessary for the Food and Drug Administration to evaluate its responsibilities to the public with respect to this basic require-

ment of a new-drug application. This led to the issuance of a statement of policy in the *Federal Register* of December 4, 1948, entitled "New Drugs Intended For Animal Use." I wish to quote only from the last paragraph of this policy statement:

> In considering a new-drug application for a product intended to effect physiological changes in farm animals, the Federal Security Agency [Department of Health, Education, and Welfare] will regard the absence of satisfactory evidence showing that the meat or other food obtained from animals fed the drug is entirely free of any poisonous or deleterious ingredient resulting therefrom at the time of marketing as ground for refusal to make the application effective.

The second necessary part of a new-drug application that I wish to touch upon briefly calls for "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." To quote from a discussion of medicated feeds by one of your colleagues, Dr. R. E. Lubbehusen of Ralston Purina Company, St. Louis, Missouri:

> But let us get back to our simple answer as to why the feed mixer has had to assume the role of pharmacist and then incidentally ventured into what was presumed to be the field of veterinary medicine. Almost all of these medicinals shared two things in common, namely, their dosage even at treatment levels was exceedingly small and certainly few were water soluble. The former called for thorough blending in a mass medium, and the latter, i. e., relative insolubility, pointed to feed as the carrier of choice . . . .
>
> If you are in the mixed feed business today, you have been forced to assume the responsibility of thoroughly blending exceedingly small amounts of medicinals in certain of your feed bases; you are clearing, labeling, registering, and selling these products not as feeds but as drugs; and, furthermore, you are assuming responsibility for results in the field that requires a basic knowledge of the fundamentals of disease control.

There is no question but what these requirements of an adequate new-drug application have placed a burden upon industry. The question may be asked: "Are these controls necessary?" We believe the answer is "yes," both from a legal standpoint and from the standpoint of public interest. Detailed regulations have been issued under the new-drug section of the law, spelling out the procedures applicable to the filing of a new-drug application. These are much too lengthy to discuss at this time but are, of course, available upon request.

By way of summary, if you are contemplating the distribution in interstate commerce of a new drug, an application should be filed with the Food and Drug Administration and be made effective before engaging in the commercial distribution of the article. The application must contain all of the information required by the law before it can

be considered by the Administration. The data submitted in such a new-drug application is considered to be the confidential property of the firm submitting it and may not be considered in reviewing other applications unless we are authorized to do so by the firm submitting the data.

Again, we are always glad to express an opinion as to whether a product is a new drug if the quantitative formula and proposed labeling are submitted. I should like to remind you of that portion of the definition of a new drug that says a product shall remain in that status until it has been used to a material extent or for a material time for its indicated purposes. This becomes important in determining when a particular type of drug loses its status as a "new drug."

"Certifiable Antibiotics"

Turning now to the third category of drugs which I mentioned earlier, the so-called "certifiable antibiotics": Before discussing the procedures under the federal law which apply to products containing such antibiotics, I should like to make two points. First, not all antibiotics are subject to the certification provisions of the law, and thus not all are classified as "certifiable antibiotics." Only those antibiotic drugs named specifically in the statute are subject to the special certification requirements. These drugs are penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, bacitracin, and chloramphenicol and derivatives thereof.

The second point I should like to emphasize is that if a medicated feed contains a certifiable antibiotic, it is not subject to the new-drug provisions of the federal law. It is dealt with under the various regulations which have been adopted dealing with antibiotic-containing drugs.

If, on the other hand, the medicated feed contains an antibiotic other than a certifiable one, the medicated feed must be considered from the standpoint of the new-drug provisions of the law, or the general drug provisions of the law, as the facts warrant. In other words, to put it, I hope, more simply, a medicated feed cannot be both a new drug and one subject to the certification provisions of the federal law.

Lest some of you fear that I am now about to launch into a lengthy discussion of antibiotic regulations, let me reassure you that I am not. I do hope to be able to point out briefly the nature of the principal

regulations which have been adopted under the certification provisions of the federal law which may be helpful should you have occasion to consult these regulations with respect to your own problems.

The statute basically requires that any article containing one of the certifiable antibiotic drugs shall either be from a batch which has been certified by the Food and Drug Administration prior to its shipment in interstate commerce or be a product which has been exempted from such a requirement by one of several types of regulations which have been issued by the Commissioner and published in the *Federal Register*. Before a regulation exempting an antibiotic-containing medicated feed can be issued, data must be submitted to the Food and Drug Administration adequate to prove that the product is safe and efficacious for use under the conditions proposed in its labeling.

In the early part of 1951, a regulation was issued exempting animal feeds containing certifiable antibiotic drugs from batch certification where the antibiotic content of the product was intended solely for growth-promotion purposes and the levels of the drug were consistent with such a purpose. These initial exempting regulations have been expanded so as to provide for the use of antibiotics in medicated feeds at levels which are effective in the prevention or treatment of certain infections in poultry, swine and calves. These latter regulations spell out the conditions for which the medicated feed may be offered in the treatment or prevention of disease, the levels at which the antibiotic must be present in the product, and other conditions which must be observed if a manufacturer is to enjoy an exemption from the general certification requirements of the law with respect to the distribution of a particular type of product. In addition, these regulations now provide for mixtures of antibiotic drugs and other drugs in medicated feeds and again set forth the conditions of use for which the product may be offered and the levels at which both the antibiotic and nonantibiotic drugs shall be present in the mixtures.

New Type of Exempting Regulation

More recently, another type of exempting regulation has been issued under the antibiotic provisions of the federal law. You will recall that I mentioned earlier that a product cannot be both a new drug and one subject to the antibiotic provisions of the statute. These newer regulations are designed to provide the same type of regulatory control over a product which would be classified as a new drug were

it not for the fact that it contained a certifiable antibiotic. These newer exempting regulations differ from the earlier regulations in that they do not provide a general exemption from the certification requirements but do require that the individual manufacturer desiring to market products under such exemptions must submit to the Commissioner evidence, that his preparation is safe and efficacious, similar to the information required in a new-drug application. An example, with which perhaps many of you are familiar, of the type of product covered by these newer exempting regulations is one containing diethylstilbestrol and one of the certifiable antibiotics.

Some of you may wish to make a note that these various regulations appear as Section 146.26 of the antibiotic regulations issued under the Federal Food, Drug, and Cosmetic Act. It is my understanding that no single section of the antibiotic regulations has been more active than this section. Since it was first issued in April, 1951, this section has been amended 40 times or more so as to include new preparations and new uses for old ones. The history of this regulation is an impressive demonstration of the rapid and extensive changes that are constantly taking place in the medicated-feed industry. They illustrate to both the feed manufacturer and the control official, as one of our field people put it, "the necessity for running pretty fast just to keep in the same place."

In retrospect, I realize that there are many phases of food and drug policy and procedure in the medicated-feed field that I have not touched upon at all. I have tried to mention some of those things which, from our correspondence, appear to be particularly troublesome. I hope that I have not confused a complex problem.

In closing, I extend to you all a sincere invitation. If you have any questions or problems arising out of the Federal Food, Drug, and Cosmetic Act, feel free to visit with us or write to us about it. We shall deal with your problems sympathetically and with an effort to be as genuinely helpful as possible. We shall do our best to assist you in meeting the requirements of the law, which we know is the objective of all of you. It is likewise our objective, and we are grateful for the opportunities such contacts afford us to do a better job for the public. **[The End]**

Food-Additive Legislation— A Review of Fundamentals

By JOHN A. GOSNELL

The Writer, an Attorney, of Washington, D. C., Was a Speaker at the Twelfth Annual Meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, Held Last January 23 at New York City

THE subject of chemicals in food has been with us for nearly two decades, and it may be noted that in spite of the alarm expressed in some quarters, the food supply is both abundant and of high quality, and the public health has prospered mightily as a direct consequence of this fact. There is no evidence either of lack of progress in the food field or lack of regard for the public safety that may be charged to any of the industries concerned.

The legislative problem of pesticides has been disposed of by the Miller Act, but the subject of food additives is again on the agenda of the Eighty-fifth Congress.

Many papers have been written on the scientific and legal aspects of this problem. In fact, the bibliography on the subject has reached astonishing proportions, and it may be that in the intensity of our concern over the particulars we have lost some degree of perspective.

There are indications that this subject is approaching the legislative boiling point, so it may be wise, if not imperative, to focus on the whole problem and to review the basic principles and facts that should determine the course of legislative action.

As to general policy, there can be no quarrel with protection of the sacred domain of public health. Indeed, the accord on this point is more apt to result in control for the sake of public relations rather than because of any real public need.

Therefore, we must at the same time take due note of an equally sacred concept that the federal regulatory power should be expanded only to the extent required by clear and impelling public necessity.

The record before us is replete with assurance that a pretesting law is needed, and the forces of logic, common sense, and especially public relations incline us to a sympathetic view. But the record may be searched in vain for evidence of the alleged public hazard, or for a definitive presentation of valid reasons justifying the enactment of any controls.

Reasons for Rapid Growth of Problem

Probably the truth is that a combination of pressures is responsible for the momentum. First is the obvious ambition of the government to control food additives; second may be the inability of industry to cope with the delicate public relations problem thereby created; third may be the involvement of industry frustrations under the so-called per-se doctrine. Of course, there have been the usual dubious insinuations that some of the motives are possibly aimed at avoidance of responsibility, or at protecting the status quo in certain areas against competition from the innovations of this chemical age.

But whatever the reasons, the gaps in the record should be filled. Our legislators should know whether, under the sacred flag of protection of the public health, the real impetus is bureaucratic ambition, selfish aims or a genuine need for modification of the present law.

"Planned Propaganda" v. Rational Consideration

Our legislators should be reminded of the irresponsible nature of most of the statements appearing in the record of the early hearings on this subject. There is abundant evidence that rational, objective thinking on matters of food policy is not frequently encountered. It may have been noted that the sensational press has again resumed publication of articles designed, through misrepresentation and exaggeration, to alarm the public and to create demand for legislation. This has happened every time this subject has come before Congress, and, since it bears the stamp of planned propaganda, it raises the question of why these dubious methods are deemed necessary to accomplish a meritorious purpose.

Assuming that there is a genuine need for legislative treatment, the next major concern should be to see that the formula employed

is entirely consistent with our traditional concepts of government and established law. This may appear to be an elementary suggestion but, even so, the need for such precaution is clearly indicated.

It may be noted that there is surprising evidence of confusion in recent government legal papers as to the difference between administrative process and administrative law. It seems to have been entirely overlooked that the chief concern of administrative law is the protection of private rights in connection with the exercise of the administrative process. This, too, may be an elementary point, but when administrative law appears to be regarded as a special property of the agencies of the government, it is high time to get back to fundamentals.

Probably the most disturbing point involved in this matter arises under the proposal that final determinations of safety shall be made by an administrative agency of the government. This formula contemplates that, while pretesting will continue to be done by industry, the final determination of the adequacy of that testing and of safety would be made by the government. Industry may do all that it considers necessary to justify the assumption of product responsibility, but if the government disagrees and a prohibitory regulation issues, that ends the matter for all practical purposes, even though recourse is had to an agency hearing and appeal.

Conflicting Concepts of Government

Just what kind of hybrid procedure do we have here? Who becomes responsible for this new product, if it ever does reach the market place—industry or the state? Let us recognize this for what it is—an attempt to follow two entirely different and conflicting concepts of government. One is the road of free enterprise and individual responsibility—the other is that of the authoritarian decision in a socialized state. Let us keep our thinking straight and see to it that this control, if needed at all, follows the American way, with industry responsibility on one side of the fence and regulatory power on the other.

There is no question but that federal regulatory authority may provide for licensing where Congress is convinced that the facts clearly justify this form of preventive action. Part of the difficulty here is that the proposed administrative action would be neither regulation nor licensing within the established concepts of administrative law.

Let us examine the true nature of the determinations of safety to be made under the administrative proposal. The new product under consideration would generally be the result of research costing many thousands of dollars. The commercial stake involved frequently may be considerable. The issue is safety as determined by the government on the basis of research performed by industry. The issue is proposed to be resolved by the procedures relating to the promulgation of regulations. But is this action in fact the development of a general rule for future application? This determination primarily affects the rights of a single applicant—and very important rights. It is regulatory only in a nominal sense. The fruits of research in this area are equally as important to the applicant, and to society, as the private rights and public policy considerations involved in the issuance of patents, a procedure protected by *de novo* judicial scrutiny of the facts involved.

In the light of these facts it would appear to be grossly inadequate to leave the final determination of these important rights to perfunctory agency hearing and the generally unavailing appeal to a circuit court.

What Does Administrative Hearing Contribute?

It is perhaps unnecessary to comment to this group on the inadequacy of the administrative hearing in this area as making any real contribution to due process. The agency-hearing officer has been aptly characterized by one of our illustrious colleagues as a "recording instrument that maintains order." It is unnecessary to say more.

With respect to review, it will be recalled that during the 1956 hearing before the Health and Science Subcommittee of the House Committee on Interstate and Foreign Commerce, the subcommittee appeared to feel that in the passage of the Administrative Procedure Act, Congress had, in effect, closed the door policywise to any special formula of review, or other judicial consideration, designed to weigh particular administrative determinations. It is submitted to the contrary that the voluminous legislative history of the act shows that it was clearly acknowledged that certain types of administrative decisions might require a closer judicial scrutiny than others, and that Congress should, by specific legislation, provide for each situation requiring special treatment. The problem here is not the complete freedom of Congress to deal with the situation, but to demonstrate: first, that the determination of safety is in effect an adjudication of

important private rights and, second, that this determination is a subjective process highly susceptible to error or arbitrary treatment. The accepted formula is that the judicial scrutiny should be commensurate with the importance of the rights involved and the probability of error.

It is suggested that, if the judicial conference had been fully informed on these points, and correctly advised as to the absence of additional burden on the federal courts, no serious objection, if any, would have been made to the declaratory judgment procedure in the 1956 hearing.

Practical Aspects

Now we come to the practical aspects of the situation. There are several basic facts that must be squarely confronted and thoughtfully weighed in connection with the administrative control plan.

First, there is a great difference in approach between industry and government in the appraisal of safety. The essence of this difference is the practical v. the theoretical. If there is any possibility of actual hazard in marketing a new product, industry will not take the risk. On the other hand, the government, on the basis of past record, is very apt to prohibit the use of a product on suspicion of a theoretical hazard.

Second, it is commonly noted that where industry is required to furnish information and data to an administrative agency of government for regulatory purposes, the inevitable result is a tendency to negative action. Wholly aside from the merits of the situation, the "processing" becomes the major grist from the administrative mill. There is involved here—also—the danger of regulation by publicity and of insinuation or, more politely, by intimation of disapproval, which is about equal to intimidation. In fact, it has been well said that any law requiring the filing of data with a regulatory agency results, in practical effect, in full control by that body.

Third, the determination of safety can never be absolute. Regardless of the extent of animal experimentation, the theoretical hazard can never be eliminated. This fact, plus the disposition not to take even the remotest chance, will inevitably result in excessive caution.

Fourth, the ultimate appraisal of hazard is primarily a matter of judgment and consequently exposed to all of the weaknesses of any subjective process.

Fifth, food improvement policy can be controlled by the imposition of prohibitive testing requirements.

Sixth, industry will not be able to control research costs. This will undoubtedly influence research to some unknown, but considerable, extent. It has been argued that the new drug law has had no such effect on research. It may be pointed out that there are impelling reasons for making a new drug quickly available to the public. The same reasons do not apply to the commercialization of a new food product.

Seventh, the companies equipped with extensive laboratories may not be too disturbed by the economic aspects of the government control of safety. On the other hand, the smaller companies may find it impossible to finance the research required by the government standards of testing.

Proposals Raise Additional Questions

There are a number of other important questions raised by the various proposals. The so-called general-recognition test has been the object of legitimate criticism. This point has been well discussed elsewhere, but it is still unsolved. The government interest in "function" or "utility" is universally opposed for very sound reasons, and needs no further comment here.

Where does this review leave us? Here: There is a need for modification of the present law on a reasonable and constructive basis. Pretesting should be required. Progress through research must not be impeded. Traditional concepts of government and established law must be fully observed. Bureaucracy should not be burdened with a responsibility that is incapable, without omniscience, of efficient or objective administration.

The legislative purpose is clear and the pitfalls are clear. The goal could be adequately achieved by a simple requirement that new food additives must be pretested for safety and that notification of intended use be given to the government prior to sale in interstate commerce. This is the maximum that ought to be required, but industry has indicated a willingness to go further.

It is submitted that the only missing element is that of genuine cooperation in compromising the differences. **[The End]**

CHRISTOPHER

COMMENTS

Thomas W. Christopher is associate dean and professor of law at Emory University, Atlanta, Georgia.

Dotterweich.—A variation on the *Dotterweich* case [1] presents the same interesting question of the liability of an officer where the corporation is found not guilty. In the present case,[2] the indictment charged a corporation and its president with shipping adulterated mushroom salt. The individual was president and chief stockholder in this corporation and a second corporation, both corporations being in the same business and doing business at the same address. At the trial, evidence showed that the shipment had been made by the second corporation, which entity was not a party to the legal proceedings. After the jury had found the first corporation and the individual guilty, the judge entered an order acquitting the corporation. On appeal by the individual, the lower court was upheld on the ground that the indictment charged the person as an individual, not as president of the first corporation.

The decision does not outline the evidence, but we may assume that the trial showed some direct link between the individual and the shipment. Vicarious liability would not explain this case, and if there were no direct link, then the decision appears to be in error. To put it another way: If the corporation goes free due to proof that the corporation did not do the act, then an individual cannot be held liable merely because he is president of the said corporation. In this respect, then, the present decision differs from *Dotterweich.*

Such a distinction, if it is sound, presents problems. For one thing, it requires the appellate court to go into the evidence. But the situation in the present case is simplified by the fact that the corporation was freed by way of the judge's ruling.

The decision has been appealed to the United States Supreme Court.

[1] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

[2] *Lelles v. U. S.*, CCH Food Drug Cosmetic Law Reports ¶ 7389, 241 F. (2d) 21 (CA-9, 1957).

The Scientists' Forum

By BERNARD L. OSER

Director, Food Research Laboratories, Inc.

Flavorigenic Chemicals

The following excerpts are from an address by Dr. Oser on "The Role of Flavor Compositions in the Current Food Additive Situation," presented on May 21, 1957, at the annual meeting of the Flavoring Extract Manufacturers Association in New York.

The list of food additives * published by the Food Protection Committee of the National Research Council includes about 500 substances of which about 300 are in the category of "Flavoring Agents: Aromatic Chemicals, Essential Oils, and others." Some 150 of these substances were described by Commissioner George P. Larrick as being in a "scientific no-man's land" with respect to our knowledge of their safety for use. There is good reason to believe that they consisted almost exclusively of flavor chemicals.

. . . The food additives bills that have been introduced in this and previous sessions of Congress require the submission of testing data by the petitioner and either notification to or approval by the Secretary of Health, Education, and Welfare, prior to use in interstate commerce. Where do flavoring agents stand under these proposed bills?

Most relevant is the provision common to all definitions of chemical additives in the various bills now before Congress, viz. that they must be safe for use under the conditions of intended use. This virtually means replacement of the unworkable and abstract per se doctrine by a realistic determination of whether the substance is harmful, i. e. in relation to the amounts and conditions of use. This new approach to the safety of food additives removes a Damoclean sword from over the heads of users of flavor chemicals which might be demonstrated to be poisonous under the exaggerated experimental conditions employed in toxicological laboratories.

Manufacturers and users of flavoring agents have hoped for a provision in the amended law granting exemption to those substances in use prior to its

* The Use of Chemical Additives in Food Processing. A Report by the Food Protection Committee of the Food and Nutrition Board. National Research Council, Publication 398 (1956).

enactment. Some of the bills have been drafted to cover only new additives, that is, they contain a grandfather clause excluding by definition those additives which were in use prior to a given date. The Administration-approved version of a food additive bill (H. R. 6747) is not quite so magnanimous toward industry although many will argue that it is more reasonable from the standpoint of public interest. This bill would exempt any additive that is "generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use." This recognition of *prolonged use* without apparent hazard as a criterion of safety for continued use, represents a substantial liberalization of viewpoint on the part of the Food and Drug Administration. It is to be noted, however, that "prolonged use" in this context would undoubtedly be predicated on conditions closely approximating, if not identical with, those contemplated in the new or intended use. Thus a flavoring agent that may have been employed with impunity in a cough syrup or in a cake icing might not qualify for exemption if it were intended to use it as a milk flavoring agent. It should not be assumed therefore that this bill will permit a listing of flavoring substances whose "prolonged use" justifies their exemption irrespective of the nature of the previous and proposed uses.

There will doubtless be some argument over the meaning of "prolonged" as there has been over the terms "generally recognized" and "qualified experts." However, there seems to be no better way to qualify such definitions than to leave something to administrative discretion and to provide for legal adjudication if it is abused.

It may be expected that the *natural presence* of chemical flavoring substances in fruits, berries, or other foods will be cited as examples of prolonged use. For example, a petitioner for ethyl caproate as an ingredient of an apple ester mixture could contend that such use was established by the demonstration of its presence in apples.

. . . Most of the compounds in current use, such as those listed in the NRC Food Protection Committee's survey, will doubtless seek shelter under the prolonged or prior use clauses of the proposed amendments, depending on which type of grandfather clause may be enacted.

Will it be possible to claim for all flavor chemicals in current use a history of prolonged, much less merely prior, use? What sort of proof will be demanded for such use? Will manufacturing or sales records of suppliers suffice or will the food processor himself be asked to make known his past practices? What about the processor who uses commercial flavor blends of composition unknown to him?

Of course many reference works are available in the field of food formulation and processing which list the names of flavor chemicals but to what extent does this prove their actual use? Furthermore can the mere name of a manufactured organic chemical suffice to establish identity with a chemical named in a formulary? Proof of identity, according to present Food and Drug Administration requirements in drug and pesticide control, goes far beyond that.

In spite of these questions surrounding the evidence of prolonged use, it may be assumed that a substantial number of flavor chemicals may enjoy exemption under one of the proposed amendments—how many, it would be unwise to predict.

It may be mentioned that current food additive bills do not differentiate among chemical additives as regards their natural or synthetic origin. From the

Organic Chemicals Used or Found in Flavoring Agents

Classes	*Total Listed*[1]	*Of Which Those Contained in FPC List Are:*	*Of Which Those Contained in Natural Products Are:*[2]
Alcohols	39	23	35
Aldehydes	36	23	13
Ketones and lactones	38	22	10
Acids	34	7	28
Ethers	13	3	—
Esters	222	127	27
Other	49	15	33
Totals	431	220	146

[1] Compiled from various reference books and catalogs.

[2] According to recently reported analyses, these figures are minimal.

viewpoint of health protection this is quite logical inasmuch as there is no a priori basis for regarding natural oils, extracts or concentrates as being harmless. Nevertheless it is reasonable to assume that prolonged use can more readily be established for essential oils as a class than for synthetic organic compounds. Aside from essential oils and similar naturally-occurring substances, the Food Protection Committee's list comprises about 220 compounds of which somewhat over one-half are esters, the balance being about equally divided among organic alcohols (including phenolic compounds), aldehydes, ketones (including lactones), and miscellaneous compounds. Many, if not most, of these are among the 150 or so compounds recently reported to be present in coffee, tea, apples, oranges, raspberries, strawberries, and other fruits which were subjected to analysis by modern methods of countercurrent extraction, chromatography, and infrared spectrophotometry.

I have deliberately avoided specifying or enumerating these compounds and checking them against lists like that of the Food Protection Committee since it must be admitted that such a list can hardly be regarded as complete. Failure to disclose the identity of all flavor additives in use as well as the non-existence or inadequacy of knowledge of the composition of at least some of them are basically responsible for this situation.

A problem common not only to flavor chemicals but to food additives generally, is, the changes that they undergo after addition to foods or during processing and subsequent aging. For instance, it is highly probable that certain flavor mixtures in use enter into reactions such as interesterification, enolization, oxidation, and polymerization as a result of which it is difficult, if not impossible, to establish the exact composition of the end products. When this situation prevails, toxicological data on the original substances must be interpreted with some reservation. In fact it has been suggested that animal research should always be directed toward the end uses, that is to say by feeding the food treated with the additive to the maximum feasible extent, rather than feeding the reactive substance itself . . . .

More on Poisons Per Se

Larrick Address to Food and Drug Officials.—In an address delivered before the annual meeting of the Association of Food and Drug

Officials of the United States in Louisville, Kentucky, last month, Commissioner George P. Larrick had the following to say in connection with food-additives legislation:

> . . . we have never had a "per se" rule against added poisons in the sense of an absolute prohibition. True, we have been successful in applying the present law against acutely toxic materials, but the big problem has been the long-term or chronic effects of chemical additives to food. For years we wrestled with the very difficult question—What is "poisonous"? Then there has been the problem of proving that a poisonous substance might render the food containing it dangerous to health. We have never been able to define "poison" without including such things as iodine or vitamins, which are essential in human nutrition. And when we tried to prove to a jury of laymen that a chemical was in fact a poisonous or deleterious substance, we inevitably had grave difficulties if we could not compare it to some well known acute poison, such as carbolic acid or strychnine. Whenever the toxic effects of the chemical were long-term effects, we found it extremely hard to communicate to judges and juries the well-known scientific fact that a poisonous substance may be one that harms vital organs when given in low doses over a protracted period of time. Poison to a layman ordinarily means something with skull and cross-bones on the bottle that will kill him immediately. It is a new thought to him that a chemical may be classified as a poison if eaten over a long period by rats and dogs without any apparent harm—yet it slowly damages their livers.
>
> If we had adopted a very strict interpretation much technological progress would have been blocked. Had we applied the law literally we might have found it changed in a way that would have lessened consumer protection and cost us our leadership in this field. By adopting a realistic policy we have been able to get the great majority of the manufacturers to bring their new additives to us for consideration by our scientists. We have been able informally to retain a must greater degree of control over the situation than would have been the case if a more rigid policy had been followed.
>
> This whole problem has been carefully considered by the scientists of the Food Protection Committee of the National Research Council. They concluded that to have progress we must have legislation which recognizes practicality. There are many substances which are toxic but can be used with entire safety to perform some useful function. A committee of the American Public Health Association studied the matter and endorsed the philosophy expressed by the National Research Council . . . ."

Court Reviews Definitions of "Poison."—His decision in a civil action involving the sale of drugs in a super market (*New Jersey State Board of Pharmacy v. Adelman*) provided Justice John D. Lynn of the Bergen County (N. J.) District Court with the occasion to delve into the definition of "poison." That the manner or conditions of administration are intrinsic to any sound definition is apparent from this analysis:

> Turning our attention now to the word "non-poisonous" we find that it does not lend itself to a clear and easy statement of its meaning, and by some authorities it is said to be incapable of definition; the situation is not a new one created by the thinking of medical men of the present day; apparently it is of long

standing and one which has plagued professional men for some years; its antonym "poisonous," is derived from the noun "poison" and the following portion of the article in the Encyclopedia Britannica, Eleventh Edition, (1910-1911), the earliest edition of that authoritative work available to the Court, regarding that word is of more than passing interest:

"*POISON.* An exact definition of the word 'poison' (derived through Fr. from Lat. *Potio, Potionem* a drink, *i. e.,* a deadly draught) is by no means easy. There is no legal definition of what constitutes a poison, and the definitions usually proposed are apt to include either too much or too little. Generally, a poison may be defined to be a substance having an inherent deleterious property, rendering it capable of destroying life by whatever avenue it is taken into the system; or it is a substance which, when it is introduced into the system, or applied externally, injures health or destroys life irrespective of mechanical means or direct thermal changes. In popular language a poison is a substance capable of destroying life when taken in small quantity; . . . .

"The ordinary action of a poison may be greatly modified by the largeness of the dose, by the state of aggregation, admixture, or of chemical combination of the poison, by the part or membrane to which it is applied, and by the condition of the patient."

In the Fourteenth Edition of the Britannica, (1937), the following is set forth as a definition of the word "poison":

"A substance which by its direct action on the mucous membrane, tissues, or skin, or after absorption into the circulatory system can, in the way in which it is administered, injuriously affect health or destroy life."

In Appleton's Medical Dictionary, (1904), poison is defined as "any substance that acts upon a living organism in such a way as to destroy its life or decidedly impair its processes," and in Wharton & Stille's Medical Jurisprudence, (1905), as "a substance having an inherent deleterious property which renders it, when taken into the system, capable of destroying life."

Lippincott's Medical Dictionary, (1905), states that a poison is "an animal, vegetable or mineral substance which, when applied externally or taken into the stomach or the circulatory system, operates such a change in the animal economy as to produce disease or death."

The American Illustrated Medical Dictionary, 22nd Edition, (1951), defines the word as follows:

"Any substance which, when ingested, inhaled or absorbed or when applied to, injected into, or developed within the body, in relatively small amounts, by its chemical action may cause damage to structure or disturbance of function."

From Stedman's Medical Dictionary, (1953), we learn that a poison is:

"Any substance which, when taken into the body in a single dose of gr. 15 (1.0) or less, is injurious to health or dangerous to life."

Probably the most recent attempt at a definition is to be found in Blakiston's New Gould Medical Dictionary, 2nd Edition, (1956):

"A substance that, being in solution in the blood or acting chemically on the blood, either destroys life or impairs seriously the function of one or more organs."

. . .

In reviewing the testimony given on the issue as to whether the fourteen drugs or medicines are poisonous or nonpoisonous within the meaning of the

statute, we find that the witnesses very definitely came to a parting of the ways and we are confronted with a contrariety of expert opinion; in short, the word "nonpoisonous" is patently ambiguous, if we are to accept the views of some of the experts who testified; whatever the generally accepted meaning of the term may be, we are mainly concerned with the specific meaning of the word as it applies to the specific fourteen products under examination . . . .

Definitions in H. R. 7388.—Of further interest in this connection are the definitions contained in Representative Curtis' bill, H. R. 7388, to regulate the distribution and sale of "packages of hazardous substances intended for household use":

(f) The term "hazardous substance" means any substance or mixture of substances which (1) is toxic, (2) is corrosive, (3) is an irritant, (4) is flammable, (5) is radioactive, or (6) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or illness during any customary or reasonably anticipated handling or use.

(g) The term "toxic" shall apply to any substance which has the inherent capacity to produce bodily injury through ingestion, inhalation, or absorption through the skin.

(h)(1) The term "poison" means any toxic substance which falls within any of the following categories: (A) produces death within forty-eight hours in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered; or (B) produces death within forty-eight hours in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of two milligrams or less per liter of gas, vapor, mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or (C) produces death within forty-eight hours in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less.

(2) If the Secretary finds that available data on human experience with any substance in the above named dosages or concentrations indicate results different from those obtained on animals, he may declare such substance to be a poison or not to be a poison for the purposes of this Act.

PRODUCT LIABILITY—DEODORANT —ALLEGED INJURY

In a recent decision, the United States Court of Appeals for the Second Circuit reversed and remanded a holding by the United States District Court for the Southern District of New York to the effect that a remote vendee of a deodorant cannot recover damages from the manufacturer for injuries sustained as a result of the plaintiff's own allergy rather than any inherent defect in the product itself. The case is reported in CCH FOOD DRUG COSMETIC LAW REPORTS, at ¶ 22,486 (Report No. 193, June 10, 1957).

STATE

FOOD AND DRUG NOTES

For the June issue of the *Journal*, we present excerpts from the report of the Special Committee to Study the New York Antitrust Laws of the New York State Bar Association. The committee's recommendations spotlight the general need for state antitrust legislation, and the role it should play in the attainment of antitrust goals. Milton Handler served as chairman of the committee.

"THE COMMITTEE'S RECOMMENDATIONS

"1. *The need for state antitrust enforcement*

"The Committee concludes, first of all, that there is a genuine need for more effective enforcement of New York's antitrust laws. The Study catalogs a substantial number of complaints received by appropriate authorities charging restrictive practices primarily of local concern, though some technically may affect interstate commerce, in areas vitally important to the citizens of this State. Notwithstanding theoretical concepts of jurisdiction, the Department of Justice and the Federal Trade Commission have not proceeded in these cases. Undoubtedly they are influenced by limitations of manpower and budget and the greater urgency of policing monopolistic practices in industries operating over many states. It is doubtful, therefore, whether these complaints will be investigated, and that such wrongs as may be found will be redressed, unless the State takes effective action. We can see no reason why these segments of our economy should not be safeguarded against restraints of trade and monopolistic restrictions.

"2. *Cooperation between state and federal governments*

"We find also that antitrust enforcement against local restraints which technically affect interstate commerce is within the concurrent jurisdiction of state and federal governments. We believe that the situation in New York calls for federal-state cooperation so that antitrust enforcement may avoid overlap of effort, conflict of jurisdiction, and unnecessary litigation as to whether the challenged activity constitutes intrastate or interstate commerce, or whether it so substantially affects interstate commerce as to be beyond state control. Therefore, if New York increases its appropriations for antitrust enforcement, as we strongly urge, we recommend that informal arrangements be made by state officials with the United States Attorney General and the Federal Trade Commission vesting in the State of New York primary responsibility for antitrust enforcement against restraint of trade in retail distribution and manufacture for essentially local consumption, as well as restraints which take place wholly within the State of New York—the principal areas in which state interest ordinarily outweighs federal. In other words, the federal government should relinquish to this State primary responsibility for restraints which do not affect the citizens of other states to a substantial degree. By this allocation the United States would be able to proceed against restraints which concern more than one state, and New York would be able to move against

restrictions within its territorial borders. In this way, there will be complete coverage.

"We recommend that the United States refer to New York all information which it possesses as to cases primarily of local concern, and that in turn New York refer to the Department of Justice all information which it may possess as to restraints of a more extensive character. We recognize that at all times, of course, where a restraint affects interstate commerce, the Department of Justice may exercise its paramount right, if it deems it necessary, to supersede state action by instituting suit under the Sherman Act. The federal government might choose to act because it is seeking judicial clarification of the law, or because for any other reason it deems federal interest predominant notwithstanding the general categories set forth above. We make this recommendation for New York alone. While we have obtained some sparse information from other states, we have not considered the situation elsewhere.

"3. *The substantive adequacy of the New York law*

"The Committee finds New York law substantively adequate for the task at hand. However, in contrasting state and federal law one is struck by the verbosity, turgidity and complexity of the New York legislative language. Were we starting from scratch, in order to avoid placing businessmen in the dilemma of having to comply with conflicting standards, we might urge the use of identical wording in both state and federal statutes. . . .

"But . . . we find no need for legislative alteration of any of the doctrines developed by the New York courts. We find the Donnelly Act an adequate substantive tool to deal with the problems of restraint of trade in this State.

"4. *The need for statutory clarification*

"We believe, however, that this state's statutory law could be vastly improved by simply eliminating the Donnelly Act's cumbrous and tautologous phraseology and by repealing other legislation which overlaps the Donnelly Act and adds nothing to it. These anachronistic statutes are General Business Law Sections 350-351 . . .; Stock Corporation Law Section 23 . . .; and subsection 6 of Section 580 of the Penal Law . . . .

"5. *Procedure and enforcement*

"In considering the substantive law, we concluded that it would be pointless to have several statutes imposing identical requirements. Similarly, we believe that consistency in enforcement would be assured if we were to follow the federal pattern which permits local federal prosecutors to initiate action, but which centralizes responsibility in the Department of Justice and calls for Departmental supervision of all cases. . . .

"6. *Statutes of limitation*

"a. *Limitation of prosecution*

"The present two year statute of limitation on criminal prosecutions is too short to permit adequate investigation of complex antitrust charges. We recommend a three year period of limitation. The comparable federal statute is five years. . . . Of course, a proviso should be appended to prevent the revival of criminal liability already barred by the existing statute. . . .

"b. *Limitation of civil action for damages*

"The Donnelly Act does not explicitly provide for a private civil suit, but the courts have on numerous occasions recognized such a cause of action. . . . To resolve these doubts and to conform state law to the federal, we recommend enactment of a four year limitation on civil suits for damages. As in the criminal limitation there should be a saving clause to prevent prejudice to existing rights. . . .

"We find no reason to recommend enactment of a special statute of limitation for equity suits commenced by the State under General Business Law Section 342 or by private litigants. . . ."

CANADA–

FOOD AND DRUG ITEMS

A trade information letter received late in May from the Canadian Department of National Health and Welfare reads, in part, as follows:

May 24, 1957—No. 153.—

"To: *Manufacturers and Packers of Food*

"Re: *Labelling and Filling of Packages.*

"Several matters related to the packaging and labelling of foods have been under consideration by the officers of the Food and Drug Directorate and the opinions of representatives of the Canadian Association of Consumers have also been obtained on these matters. It was felt that the objectionable features of some of the packages and labels now on the market should be drawn to the attention of manufacturers and packagers and their comments requested. It is felt that some action must be taken . . . as soon as possible.

"1. *Slack-fill.* . . . Food and Drug inspectors have noted on the market a considerable number of products that are slack-filled. . . . It is realized that some . . . products will pack together considerably after filling due to shaking of packages during handling, transport, etc. Nevertheless when these packages were emptied and all the contents repacked loosely, there was still considerable "head space" or vacant space in the package. Such packages should be full when they come from the packaging machine. . . .

"There are some candy . . . packages that are definitely slack-filled. . . .

"2. *Declaration of net contents.* The Directorate and the Canadian Association of Consumers believe that the net contents of many packages are not shown in a legible and conspicuous manner. It is believed that the declaration of net contents should be shown on the main panel of the label either in conjunction with the name of the product or in close proximity to it. . . .

"There are a number of mandatory requirements for food labels. . . .

"The Food and Drug Directorate is giving consideration to recommending an amendment to the Food and Drug regulations with a view to obtaining prominent display of all statements required on food labels so that they may be quickly and easily seen at a glance.

"3. *Specialty products.* Consumers would like to have the volume or size of finished food given for such products as jelly powders, pudding powders, pie fillings, cake mixes, milk powders, etc. . . .

"4. *Odd sizes.* Considerable objection was raised by consumers to the packaging of foods in sizes such as 3¾ oz., 5½ oz., since the fractional amounts make it difficult or impossible to compare price and value of different brands or products.

"5. If premiums are contained in a package they should be wrapped in such a manner that there can be no hazard to health as would occur through the accidental consumption of either the whole or part of the article.

"All of these objections to the present methods of packaging and suggestions made seem to be reasonable. I would much appreciate your comments at your early convenience and not later than July 1st.

"C. A. Morrell, DIRECTOR, FOOD and DRUG DIRECTORATE."

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